

Application

(Original)

**West Cancer Center
Germantown (Shelby Co.)**

CN1808-038



Waller Lansden Dortch & Davis, LLP
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P.O. Box 198966
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Kim Harvey Looney
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August 15, 2018

VIA HAND DELIVERY

Melanie M. Hill
Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson Building
9th Floor
502 Deaderick Street
Nashville TN 37243

Re: West Cancer Center, 7945 Wolf River Road, Germantown, Shelby County,
Tennessee

Dear Melanie:

Please be advised that West Cancer Center (the "Applicant") requests that the application be placed on the consent calendar for the October 24, 2018 hearing. This application is for the change of ownership of existing equipment and initiation of PET by West Clinic, dba West Cancer Center. West Clinic is already providing these services to its existing patients at this same location, and has been doing so in collaboration with Methodist and UT. Methodist has been billing the services as provider-based. The primary difference is that the equipment will now be owned by the West Clinic and the West Clinic will bill for these services as part of its practice. Because the primary difference in the provision of these services is the transfer of ownership of the equipment to West Clinic, the applicant would like to request to be on the consent calendar

If you have any questions or need any additional information, please do not hesitate to call me.

Sincerely,

Kim Harvey Looney

KHL:lag



State of Tennessee

Health Services and Development Agency

Andrew Jackson Building, 9th Floor, 502 Deaderick Street, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

CERTIFICATE OF NEED APPLICATION--PET/LINEAR-Germantown

SECTION A: APPLICANT PROFILE

1. **Name of Facility, Agency, or Institution**

West Cancer Center

Name

7945 Wolf River Rd

Shelby

Street or Route

County

Germantown

TN

38138

City

State

Zip Code

Website address: www.westcancercenter.org *Note: The facility's name and address **must be** the name and address of the project and **must be** consistent with the Publication of Intent.*

2. **Contact Person Available for Responses to Questions**

Kim H. Looney, Esq.

Attorney

Name

Title

Waller Lansden Dortch & Davis LLP

kim.looney@wallerlaw.com

Company Name

Email address

511 Union Street, Suite 2700

Nashville

TN

37219

Street or Route

City

State

Zip Code

Attorney

615-850-8722

615-244-6804

Association with Owner

Phone Number

Fax Number

NOTE:

Section A is intended to give the applicant an opportunity to describe the project. **Section B** addresses how the project relates to the criteria for a Certificate of Need by addressing: Need, Economic Feasibility, and the Contribution to the Orderly Development of Health Care.

Please answer all questions on **8½" X 11" white paper, clearly typed and spaced, single or double-sided, in order and sequentially numbered. In answering, please type the question and the response.** All questions must be answered. If an item does not apply, please indicate "N/A" (not applicable). **Attach appropriate documentation as an Appendix at the end of the application and reference the applicable Item Number on the attachment, i.e., Attachment A.1, A.2, etc. The last page of the application should be a completed signed and notarized affidavit.**

3. SECTION A: EXECUTIVE SUMMARY

A. Overview

Please provide an overview not to exceed three pages in total explaining each numbered point.

- 1) Description – Address the establishment of a health care institution, initiation of health services, bed complement changes, and/or how this project relates to any other outstanding but unimplemented certificates of need held by the applicant;

Response: West Cancer Center is the region's comprehensive leader in adult cancer care and research, delivering a complete continuum of care to more than 30,000 individuals each year. A multidisciplinary team approach coupled with a full-spectrum of care and support services ensures that its patients are receiving the most innovative – and comprehensive – care available. West Cancer Center is currently a collaboration between Methodist LeBonheur Healthcare ("Methodist"), the University of Tennessee Health Science Center ("UT"), and the West Clinic. Partly as a result of the shift in Medicare reimbursement for oncology services, this business relationship is set to unwind effective January 1, 2019. Since the equipment is currently owned by Methodist and billed as an outpatient department of the hospital, it is necessary for the West Cancer Center to apply for a CON for the initiation of PET and linear accelerator services, even though they are existing services. There is one PET/CT scanner and two linear accelerators at this location of the West Cancer Center. This equipment is already in operation and being used by the West Clinic for its patients.

It is the applicant's understanding that only one other scanner in the county is a PET/CT, and it is located at Baptist. The benefits of being able to offer PET/CT for cancer patients are numerous, and it is generally considered the standard of care. PET/CT technology integrates the molecular-level diagnostic capabilities of positron emission tomography (PET) with computed tomography (CT) to produce anatomic views, a practice known as image fusion or co-registration. These views allow clinical information from two different exams to be correlated and interpreted on one image, leading to more precise information and accurate diagnoses. PET/CT is prevalent in diagnosing and monitoring progression/regression of cancer.

The integration of these technologies is key to both the early detection of cancer, as well as to the treatment plan to follow. PET/CT scans generally take longer than PET scans because you are using two imaging modalities at one time, rather than just one. The linear accelerators are then used to provide treatment for the identified cancer.

Upon approval of this application, the West Clinic will purchase the equipment and integrate it into its practice as part of the West Cancer Center. Please note that a companion application for the initiation of PET services with the use of a PET/CT scanner is being filed simultaneously with this application for the West Cancer Center's location on Union Avenue. The approval of each of these applications will enable the West Clinic to continue to provide the comprehensive adult cancer care and treatment for which it is known. It would be extremely disruptive to cancer diagnosis and treatment for patients in the service area if this application and its companion application were not to be approved.

2) Ownership Structure;

Response: West Cancer Center is a dba for the comprehensive cancer services operated by the West Clinic, which is a professional corporation that has been in existence for almost 40 years.

3) Service Area:

Response: Based on the applicant's existing patient base, the service area is Shelby County.

4) Existing similar service providers;

Response: While there are four PET scanners in Shelby County, with the exception of the ones provided by West Cancer Center at its two locations, it is the applicant's understanding that only one other scanner in the county is a PET/CT, and it is located at Baptist. The benefits of being able to offer PET/CT for cancer patients are numerous, and it is generally considered the standard of care. The integration of these technologies is key to both the early detection of cancer, as well as to the treatment plan to follow. PET/CT scans generally take longer than PET scans because you are using two imaging modalities at one time, rather than just one.

There are nine linear accelerators in operation in Shelby County, including the two at the West Clinic site in Germantown. While the other linear accelerators may offer the same treatment option, none of the others do so in the same manner that the West Clinic does - as part of a comprehensive cancer center, which provides added benefits to patients.

5) Project Cost;

Response: The Applicant anticipates the project cost of the project to be \$12,017,055.02, which includes the filing fee of \$68,703.02. While the costs will be FMV, an appraisal has not yet been completed. Therefore, in order to provide a conservative cost of the project, the applicant has included the original purchase price of the equipment, and the book value of the property. The FMV is anticipated to be lower than what is listed in the application in the Project Costs Chart.

6) Funding; and

Response: The Applicant anticipates obtaining a commercial loan for the purchase of the equipment and the building.

7) Financial Feasibility including when the proposal will realize a positive financial margin; and

Response: Because the application seeks only to change the ownership of certain equipment but will continue to provide the same services to the same patient base, the project will have a positive financial margin in the first year.

8) Staffing.

Response: The Applicant will provide appropriate staffing for this project, consistent with the staffing that is already provided. Certain of the staff are currently employed by Methodist and this staff will transition to employment by the West Clinic when this project is implemented.

B. Rationale for Approval

A certificate of need can only be granted when a project is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, will provide health care that meets appropriate quality standards, and will contribute to the orderly development of adequate and effective health care in the service area. This section should provide rationale for each criterion using the data and information points provided in Section B. of this application. Please summarize in one page or less each of the criteria:

1) Need;

Response: West Cancer Center is the region's comprehensive leader in adult cancer care and research. It delivers a complete continuum of care to over 30,000 adults each year. In 1979, the doors of what would later become West Clinic officially opened when William H. West, M.D., a nationally respected oncologist and lead investigator for the National Institutes of Health in Washington, DC, lost his mother to breast cancer. He decided he wanted to provide world-class cancer treatment and research capabilities in his hometown of Memphis, Tennessee. The practice continued to grow, and relocated several times, building a reputation for both clinical excellence and cutting edge research. This led to an innovative partnership with Methodist and UT.

While the parties have decided that this partnership will end effective January 1, 2019, the need for the delivery of these comprehensive cancer services continues. From a clinical perspective, it is extremely beneficial to the patient and his/her family members when the radiation oncologists and medical oncologists are in the same practice and can participate in care coordination, which includes having the ability to diagnose and treat within the same group.

The initiation of PET services through the use of the PET/CT scanner, and linear accelerator service with equipment that is already in operation is vital to continuing to meet the health care needs of the service area residents. The benefits of being able to offer PET/CT for cancer patients are numerous, and it is generally considered the standard of care. PET/CT technology integrates the molecular-level diagnostic capabilities of positron emission tomography (PET) with computed tomography (CT) to produce anatomic views, a practice known as image fusion or co-registration. These views allow clinical information from two different exams to be correlated and interpreted on one image, leading to more precise information and accurate diagnoses. PET/CT is prevalent in diagnosing and monitoring progression/regression of cancer.

The integration of these technologies is key to both the early detection of cancer, as well as to the treatment plan to follow. PET/CT scans generally take longer than PET scans because you are using two imaging modalities at one time, rather than just one. The linear accelerators are then used to provide treatment for the identified cancer.

Shelby County is lucky to have the West Cancer Center and The West Clinic available to provide these important diagnostic services. This application is being filed at the same time as an application for PET services at the Union Avenue location of the West Cancer Center in Memphis. Together, these two sites provide both diagnostic and treatment services for cancer patients.

2) Economic Feasibility;

Response: The project is financially feasible; the costs of the project are reasonable and the applicant expects to have a positive cash flow in the first year.

3) Appropriate Quality Standards; and

Response: The West Clinic adheres to appropriate quality standards both in its practice and in the operation of this equipment. It performs quality assurance on a regular basis for the PET/CT and linear accelerator equipment.

4) Orderly Development to adequate and effective health care.

Response: These important health care services are already being provided to the patients of the West Clinic, just as a part of an outpatient department of Methodist, rather than as a part of the West Clinic practice. As their business arrangement is scheduled to be unwound effective January 1, 2019, it is important that the patients of the West Clinic continue to receive these diagnostic and treatment options close to home. It would be disruptive to patient care if this application were not approved.

C. Consent Calendar Justification

If Consent Calendar is requested, please provide the rationale for an expedited review.

A request for Consent Calendar must be in the form of a written communication to the Agency's Executive Director at the time the application is filed.

Response: This proposed project is for the change of ownership of existing equipment and the initiation of PET and linear accelerator services by West Clinic, dba West Cancer Center. West Clinic is already providing these services to its existing patients at this same location, and has been doing so in collaboration with Methodist and UT. Methodist has been billing the services as provider-based. The primary difference is that the equipment will now be owned by the West Clinic and the West Clinic will bill for these services as part of its practice. Because the primary difference in the provision of these services is the transfer of ownership of the equipment to West Clinic, the applicant would like to request to be on the consent calendar and has submitted a letter to Melanie Hill at the time of filing this application.

4. SECTION A: PROJECT DETAILS

A. Owner of the Facility, Agency or Institution

West Clinic, PC

Name

7945 Wolf River Rd

Street or Route

Germantown

City

TN

State

Shelby

County

38138

Zip Code

B. Type of Ownership of Control (Check One)

A. Sole Proprietorship ☐

B. Partnership ☐

C. Limited Partnership ☐

D. Corporation (For Profit) ☐

E. Corporation (Not-for-Profit) ☐

F. Government (State of TN
or Political Subdivision) ☐

G. Joint Venture ☐

H. Limited Liability Company ☐

I. Other (Specify) ☒

Professional corporation

Attach a copy of the partnership agreement, or corporate charter and certificate of corporate existence. Please provide documentation of the active status of the entity from the Tennessee Secretary of State's web-site at <https://tnbear.tn.gov/ECommerce/FilingSearch.aspx>. **Attachment Section A-4A.**

Response: See copy of entity information included as Attachment A-4A.

Describe the existing or proposed ownership structure of the applicant, including an ownership structure organizational chart. Explain the corporate structure and the manner in which all entities of the ownership structure relate to the applicant. As applicable, identify the members of the ownership entity and each member's percentage of ownership, for those members with 5% ownership (direct or indirect) interest.

5. Name of Management/Operating Entity (If Applicable)

Not applicable

Name

Street or Route

County

City

State

Zip Code

Website address: www.westcancercenter.org

For new facilities or existing facilities without a current management agreement, attach a copy of a draft management agreement that at least includes the anticipated scope of management services to be provided, the anticipated term of the agreement, and the anticipated management fee payment methodology and schedule. For facilities with existing management agreements, attach a copy of the fully executed final contract. **Attachment Section A-5.**

Response: Not applicable.

6A. Legal Interest in the Site of the Institution (Check One)

- | | | |
|-------------------------|---|--------------------------|
| A. Ownership | | D. Option to Lease |
| B. Option to Purchase | X | E. Other (Specify) _____ |
| C. Lease of _____ Years | | |

Check appropriate line above: For applicants or applicant's parent company/owner that currently own the building/land for the project location, attach a copy of the title/deed. For applicants or applicant's parent company/owner that currently lease the building/land for the project location, attach a copy of the fully executed lease agreement. For projects where the location of the project has not been secured, attach a fully executed document including Option to Purchase Agreement, Option to Lease Agreement, or other appropriate documentation. Option to Purchase Agreements **must include** anticipated purchase price. Lease/Option to Lease Agreements **must include** the actual/anticipated term of the agreement **and** actual/anticipated lease expense. The legal interests described herein **must be valid** on the date of the Agency's consideration of the certificate of need application.

Response: See copy of Option to Purchase and Deed included as Attachment A-6A.

6B. Attach a copy of the site's plot plan, floor plan, and if applicable, public transportation route to and from the site on an 8 1/2" x 11" sheet of white paper, single or double-sided. DO NOT SUBMIT BLUEPRINTS. Simple line drawings should be submitted and need not be drawn to scale.

- 1) Plot Plan **must** include:
 - a. Size of site (***in acres***);
 - b. Location of structure on the site;
 - c. Location of the proposed construction/renovation; and
 - d. Names of streets, roads or highway that cross or border the site.

Response: See plot plan included as Attachment 6B-1.

- 2) Attach a floor plan drawing for the facility which includes legible labeling of patient care rooms (noting private or semi-private), ancillary areas, equipment areas, etc. On an 8 1/2 by 11 sheet of paper or as many as necessary to illustrate the floor plan.

Response: See floor plan included as Attachment 6B-2.

- 3) Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients.

Attachment Section A-6A, 6B-1 a-d, 6B-2, 6B-3.

Response: The site is located on Wolf River Parkway, just off of Germantown Road, both of which are major roadways in Germantown. It is the same location as the primary practice site for the West Clinic, P.C. West Clinic has found it to be a convenient location for it patients and family members, the majority of whom arrive at this location by car. There is bus service in the area, but it stops a couple of blocks from the practice site.

7. **Type of Institution** (Check as appropriate--more than one response may apply)

- | | |
|--|--|
| A. Hospital (Specify) _____ | I. Nursing Home _____ |
| B. Ambulatory Surgical Treatment Center (ASTC), Multi-Specialty _____ | J. Outpatient Diagnostic Center _____ |
| C. ASTC, Single Specialty _____ | K. Recuperation Center _____ |
| D. Home Health Agency _____ | L. Rehabilitation Facility _____ |
| E. Hospice _____ | M. Residential Hospice _____ |
| F. Mental Health Hospital _____ | N. Non-Residential Methadone Facility _____ |
| G. Mental Health Residential Treatment Facility _____ | O. Birthing Center _____ |
| H. Mental Retardation Institutional Habilitation Facility (ICF/MR) _____ | P. Other Outpatient Facility (Specify) _____ |
| | Q. Other (Specify) <u>physician practice</u> X |

Check appropriate lines(s).

8. **Purpose of Review** (Check) as appropriate--more than one response may apply)

- | | |
|--|---|
| A. New Institution _____ | G. Change in Bed Complement _____ |
| B. Replacement/Existing Facility _____ | [Please note the type of change by underlining the appropriate response: Increase, Decrease, Designation, Distribution, Conversion, Relocation] |
| C. Modification/Existing Facility _____ | |
| D. Initiation of Health Care Service as defined in TCA § 68-11-1607(4) (Specify) <u>PET & linear accelerator</u> X | H. Change of Location _____ |
| E. Discontinuance of OB Services _____ | I. Other (Specify) _____ |
| F. Acquisition of Equipment _____ | |

9. **Medicaid/TennCare, Medicare Participation**

MCO Contracts [Check all that apply]

X AmeriGroup X United Healthcare Community Plan X BlueCare X TennCare Select

Medicare Provider Number: TN: 3704066; MS: C00622; AR 259367

Medicaid Provider Number: TN: 217965002; MS: 09013755; AR 217965002

Certification Type: physician practice

If a new facility, will certification be sought for Medicare and/or Medicaid/TennCare?

Medicare ___Yes ___No X N/A Medicaid/TennCare ___Yes ___No X N/A

10. Bed Complement Data

A. Please indicate current and proposed distribution and certification of facility beds. **Response:** Not applicable.

	<i>Current Licensed</i>	<i>Beds Staffed</i>	<i>Beds Proposed</i>	<i>*Beds Approved</i>	<i>**Beds Exempted</i>	<i><u>TOTAL Beds at Completion</u></i>
1) Medical						
2) Surgical						
3) ICU/CCU						
4) Obstetrical						
5) NICU						
6) Pediatric						
7) Adult Psychiatric						
8) Geriatric Psychiatric						
9) Child/Adolescent Psychiatric						
10) Rehabilitation						
11) Adult Chemical Dependency						
12) Child/Adolescent Chemical Dependency						
13) Long-Term Care Hospital						
14) Swing Beds						
15) Nursing Home – SNF (Medicare only)						
16) Nursing Home – NF (Medicaid only)						
17) Nursing Home – SNF/NF (dually certified Medicare/Medicaid)						
18) Nursing Home – Licensed (non-certified)						
19) ICF/IID						
20) Residential Hospice						
TOTAL						
<i>*Beds approved but not yet in service **Beds exempted under 10% per 3 year provision</i>						

B. Describe the reasons for change in bed allocations and describe the impact the bed change will have on the applicant facility's existing services. **Attachment Section A-10. Response:** Not applicable.

C. Please identify all the applicant's outstanding Certificate of Need projects that have a licensed bed change component. If applicable, complete chart below. **Response:** Not applicable.

CON Number(s)	CON Expiration Date	Total Licensed Beds Approved

11. **Home Health Care Organizations** – Home Health Agency, Hospice Agency (excluding Residential Hospice), identify the following by checking all that apply: **Response:** Not applicable.

	Existing Licensed County	Parent Office County	Proposed Licensed County		Existing Licensed County	Parent Office County	Proposed Licensed County
Anderson	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Lauderdale	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bedford	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Lawrence	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Benton	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Lewis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bledsoe	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Lincoln	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Blount	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Loudon	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bradley	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	McMinn	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Campbell	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	McNairy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cannon	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Macon	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Carroll	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Madison	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Carter	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Marion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cheatham	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Marshall	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Chester	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Maury	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Claiborne	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Meigs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Clay	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Monroe	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cocke	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Montgomery	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Coffee	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Moore	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Crockett	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Morgan	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cumberland	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Obion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Davidson	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Overton	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Decatur	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Perry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DeKalb	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Pickett	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dickson	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Polk	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dyer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Putnam	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fayette	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Rhea	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fentress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Roane	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Franklin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Robertson	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Gibson	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Rutherford	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Giles	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Scott	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Grainger	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sequatchie	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Greene	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sevier	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Grundy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Shelby	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hamblen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Smith	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hamilton	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Stewart	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hancock	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sullivan	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hardeman	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sumner	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hardin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Tipton	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hawkins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Trousdale	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Haywood	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Unicoi	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Henderson	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Union	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Henry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Van Buren	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hickman	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Warren	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Houston	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Washington	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Humphreys	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Wayne	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Jackson	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Weakley	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Jefferson	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	White	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Johnson	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Williamson	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Knox	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Wilson	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lake	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				

12. Square Footage and Cost Per Square Footage Chart

Response: Not applicable

[illegible]

* The Total Construction Cost should equal the Construction Cost reported on line A5 of the Project Cost Chart.

** Cost per Square Foot is the construction cost divided by the square feet. Please do not include contingency costs.

13. MRI, PET, and/or Linear Accelerator

1. Describe the acquisition of any Magnetic Resonance Imaging (MRI) scanner that is adding a MRI scanner in counties with population less than 250,000 or initiation of pediatric MRI in counties with population greater than 250,000 and/or

Response: The applicant is not required to receive a CON for MRI services because it is in a county with a population greater than 250,000 and it does not provide pediatric services.

2. Describe the acquisition of any Positron Emission Tomographer (PET) or Linear Accelerator if initiating the service by responding to the following:

A. Complete the chart below for acquired equipment.

<input checked="" type="checkbox"/> Linear Accelerator #1 Infinity Acquired 12/20/15	Mev <u>6, 9, 12, 15, 18</u>	Types: <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div> <input type="checkbox"/> SRS <input checked="" type="checkbox"/> IGRT </div> <div> <input checked="" type="checkbox"/> IMRT <input checked="" type="checkbox"/> Other </div> <div> <u>SBRT</u> </div> </div>	
<input checked="" type="checkbox"/> By Purchase		<input type="checkbox"/> By Lease	Expected Useful Life (yrs) <u>15</u>
Total Cost*: <u>\$2,367,971</u>	<input type="checkbox"/> New	<input type="checkbox"/> Refurbished	<input checked="" type="checkbox"/> If not new, how old? (yrs) <u>3</u>
<input type="checkbox"/> MRI-Not Applicable	Tesla: _____	Magnet: _____	<div> <input type="checkbox"/> Breast <input type="checkbox"/> Open <input type="checkbox"/> Other </div> <div> <input type="checkbox"/> Extremity <input type="checkbox"/> Short Bore </div>
<input type="checkbox"/> By Purchase		<input type="checkbox"/> By Lease	Expected Useful Life (yrs) _____
Total Cost*: _____	<input type="checkbox"/> New	<input type="checkbox"/> Refurbished	<input type="checkbox"/> If not new, how old? (yrs) _____
<input type="checkbox"/> PET	<input type="checkbox"/> PET only	<input type="checkbox"/> PET/CT	<input type="checkbox"/> PET/MRI
<input type="checkbox"/> By Purchase		<input type="checkbox"/> By Lease	Expected Useful Life (yrs) _____
Total Cost*: _____	<input type="checkbox"/> New	<input type="checkbox"/> Refurbished	<input type="checkbox"/> If not new, how old? (yrs) _____

* As defined by Agency Rule 0720-9-.01(13)

<input checked="" type="checkbox"/>	Linear Accelerator #2 Versa Acquired 12/20/15	Mev <u>6, 9, 12, 15, 18</u>	Types:	<input checked="" type="checkbox"/> SRS <input checked="" type="checkbox"/> IMRT <input checked="" type="checkbox"/> IGRT <input checked="" type="checkbox"/> Other <u>SBRT</u> <input checked="" type="checkbox"/> By Purchase <input type="checkbox"/> By Lease Expected Useful Life (yrs) <u>15</u> <input type="checkbox"/> If not new, how old? (yrs) <u>3</u>
		Total Cost*: <u>\$2,963,133</u>		
		<input type="checkbox"/> New <input type="checkbox"/> Refurbished		

<input type="checkbox"/>	MRI-Not Applicable	Tesla: _____	Magnet: _____	<input type="checkbox"/> Breast <input type="checkbox"/> Extremity <input type="checkbox"/> Open <input type="checkbox"/> Short Bore <input type="checkbox"/> Other <input type="checkbox"/> By Purchase <input type="checkbox"/> By Lease Expected Useful Life (yrs) _____ <input type="checkbox"/> If not new, how old? (yrs) _____
		Total Cost*: _____		
		<input type="checkbox"/> New <input type="checkbox"/> Refurbished		

<input checked="" type="checkbox"/>	PET	<input type="checkbox"/> PET only <input checked="" type="checkbox"/> PET/CT <input type="checkbox"/> PET/MRI	<input checked="" type="checkbox"/> By Purchase <input type="checkbox"/> By Lease Expected Useful Life (yrs) <u>15</u> <input checked="" type="checkbox"/> If not new, how old? (yrs) <u>7</u>
		Total Cost*: <u>\$1,412,602</u>	
		<input type="checkbox"/> New <input type="checkbox"/> Refurbished	
	Acquired 2/2011		

* As defined by Agency Rule 0720-9-.01(13)

- B. In the case of equipment purchase, include a quote and/or proposal from an equipment vendor. In the case of equipment lease, provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments along with the fair market value of the equipment.

Response: The equipment - both the two linear accelerators and the PET/CT scanner - is not being purchased from a vendor. The equipment is already in use and will be purchased from Methodist at fair market value. Since an appraisal to determine FMV has not yet been completed, the applicant is using the cost of the equipment when it was first purchased several years ago, which should be more than its current FMV.

- C. Compare lease cost of the equipment to its fair market value. Note: Per Agency Rule, the higher cost must be identified in the project cost chart.

Response: Not applicable. The equipment is not being leased but will be purchased at FMV. As stated above, the applicant is including the original cost of the equipment because the appraisal has not yet been completed. The FMV should be less than the original cost of the equipment.

D. Schedule of Operations:

Location	Days of Operation (Sunday through Saturday)	Hours of Operation (example: 8 am – 3 pm)
Fixed Site (Applicant)	Monday-Saturday	8:00 a.m.--5:00 p.m.
Mobile Locations (Applicant)	Not applicable	Not applicable
(Name of Other Location)		
(Name of Other Location)		

Response:

- E. Identify the clinical applications to be provided that apply to the project.

Response: The clinical applications of the linear accelerator include stereotactic radiation therapy (SRT), stereotactic body radiation therapy (SBRT) intensity modulated radiation therapy (IMRT), image-guided radiation therapy (IGRT) and treatment planning simulations.

PET/CT technology integrates the molecular-level diagnostic capabilities of positron emission tomography (PET) with computed tomography (CT) to produce anatomic views, a practice known as image fusion or co-registration. These views allow clinical information from two different exams to be correlated and interpreted on one image, leading to more precise information and accurate diagnoses. PET/CT is prevalent in diagnosing and monitoring progression/regression of cancer.

- F. If the equipment has been approved by the FDA within the last five years provide documentation of the same.

Response: Not applicable. This equipment is already operational and in use for the patients of the West Clinic.

SECTION B: GENERAL CRITERIA FOR CERTIFICATE OF NEED

In accordance with T.C.A. § 68-11-1609(b), “no Certificate of Need shall be granted unless the action proposed in the application for such Certificate is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, will provide health care that meets appropriate quality standards, and will contribute to the orderly development of health care.” Further standards for guidance are provided in the State Health Plan developed pursuant to T.C.A. § 68-11-1625.

The following questions are listed according to the four criteria: (1) Need, (2) Economic Feasibility, (3) Applicable Quality Standards, and (4) Contribution to the Orderly Development of Health Care. Please respond to each question and provide underlying assumptions, data sources, and methodologies when appropriate. Please type each question and its response on an 8 1/2" x 11" white paper, single-sided or double sided. All exhibits and tables must be attached to the end of the application in correct sequence identifying the question(s) to which they refer, unless specified otherwise. ***If a question does not apply to your project, indicate “Not Applicable (NA).”***

QUESTIONS

SECTION B: NEED

- A. Provide a response to each criterion and standard in Certificate of Need Categories in the State Health Plan that are applicable to the proposed project. Criteria and standards can be obtained from the Tennessee Health Services and Development Agency or found on the Agency’s website at <http://www.tn.gov/hsda/article/hsda-criteria-and-standards>.

MEGAVOLTAGE RADIATION THERAPY SERVICES

1. **Utilization Standards for MRT Units.**

- a. Linear Accelerators not dedicated to performing SRT and/or SBRT procedures:
- i. Full capacity of a Linear Accelerator MRT Unit is 8,736 procedures, developed from the following formula: 3.5 treatments per hour, times 48 hours (6 days of operation, 8 hours per day, or 5 days of operation, 9.6 hours per day), times 52 weeks.

Response: The Applicant will be operating two dedicated linear accelerators. Neither unit is limited to providing solely stereotactic radiation therapy (SRT) or stereotactic body radiation therapy (SBRT). In addition to SRT and SBRT, the units are deployed to provide intensity modulated radiation therapy (IMRT), image-guided radiation therapy (IGRT) and treatment planning simulations.

The existing linear accelerators performed approximately an average of over 9,100 treatments per unit in 2016, which is well above the 8,763 annual procedure/treatment standard for MRT use.

- ii. Linear Accelerator Minimum Capacity: 6,000 procedures per Linear Accelerator MRT Unit annually, except as otherwise noted herein.

Response: The Applicant anticipates significantly more than 6,000 procedures per scanner annually as it is already performing more than that number.

- iii. Linear Accelerator Optimal Capacity: 7,688 procedures per Linear Accelerator MRT Unit annually, based on a 12% average downtime per MRT unit during normal business hours annually.

Response: The Applicant anticipates greater than 7,688 procedures in the first year, since the 2 scanners are already performing approximately 9,100 treatments per scanner.

- iv. An applicant proposing a new Linear Accelerator should project a minimum of at least 6000 MRT procedures in the first year of service in its Service Area, building to a minimum of 7,688 procedures per year by the third year of service and for every year thereafter.

Response: Not applicable. This is not a new Linear Accelerator, but is already in existence. The Applicant, however, does anticipate that its utilization will be significantly in excess of 6,000 procedures because there are already more than an average of 9,100 treatments per scanner being performed on the existing scanners.

- b. For Linear Accelerators dedicated to performing only SRT procedures, full capacity is 500 annual procedures.

Response: Not applicable.

- c. For Linear Accelerators dedicated to performing only SR'17 SBRT procedures, full capacity is 850 annual *procedures*.

Response: Not applicable.

- d. An exception to the standard number of procedures may occur as new or improved technology and equipment or new diagnostic applications for Linear Accelerators develop. An applicant must demonstrate that the proposed Linear Accelerator offers a unique and necessary technology for the provision of health care services in the proposed Service Area.

Response: Not applicable.

- e. Proton Beam MRT Units. As of the date of the approval and adoption of these Standards and Criteria, insufficient data are available to enable detailed utilization standards to be developed for Proton Beam MRT Units.

Response: Not applicable.

2. Need Standards for MRT Units.

- a. For Linear Accelerators not dedicated solely to performing SRT and/or SBRT procedures, need for a new Linear Accelerator in a proposed Service Area shall be demonstrated if the average annual number of Linear Accelerator procedures performed by existing Linear Accelerators in the proposed Service Area exceeds 6,000.

Response: There are 10 linear accelerators in Shelby County, excluding the two at St. Jude's, which are limited to pediatric patients. These scanners performed an average of 4,940 per scanner in 2016. The linear accelerators at the West Cancer Center performed an average of over 9,100 treatments per scanner, significantly higher than 6,000 per scanner. Because these scanners are already operating at such a high capacity, there is no reason to think that they are not needed in the service area to continue to serve the patient population of the West Clinic. Not to allow them to continue in operation would be disruptive to meeting the health care need for cancer services of residents of the service area.

- b. For Linear Accelerators dedicated to performing only SRT procedures, need in a proposed Service Area shall be demonstrated if the average annual number of MRT procedures performed by existing Linear Accelerators dedicated to performing only SRT procedures in a proposed Service Area exceeds 300, based on a full capacity of 500 annual procedures.

Response: Not applicable.

- c. For Linear Accelerators dedicated to performing only SRT/SBRT procedures, need in a proposed Service Area shall be demonstrated if the average annual number of MRT procedures performed by existing Linear Accelerators dedicated to performing only SRT/SBRT procedures in a proposed Service Area exceeds 510, based on a full capacity of 850 annual procedures.

Response: Not applicable.

- d. Need for a new Proton Beam MRT Unit: Due to the high cost and extensive service areas that are anticipated to be required for these MRT Units, an applicant proposing a new Proton Beam MRT Unit shall provide information regarding the utilization and service areas of existing or planned Proton Beam MRT Units' utilization and service areas (including those that have received a CON), if they provide MRT services in the proposed Service Area and if that data are available, and the impact its application, if granted, would have on those other Proton Beam MRT Units.

Response: Not applicable.

- e. An exception to the need standards may occur as new or improved technology and equipment or new diagnostic applications for MRT Units develop. An applicant must demonstrate that the proposed MRT Unit offers a unique and necessary technology for the provision of health care services in the proposed Service Area.

Response: Not applicable.

3. Access to MRT Units.

- a. An MRT unit should be located at a site that allows reasonable access for residents of the proposed Service Area.

Response: The MRT units are conveniently located in the West Cancer Center building, 7945 Wolf River Road, Germantown, a suburb of Memphis, TN.

- b. An applicant for any proposed new Linear Accelerator should document that the proposed location of the Linear Accelerator is within a 45 minute drive time of the majority of the proposed Service Area's population.

Response: Although these are not new linear accelerators, the primary service area of the linear accelerators is Shelby County. This Germantown location is located within 25 miles of all Shelby County locations and within 5 miles of the largest metropolitan center in the service area, Memphis. The linear accelerators are positioned well within 45-minutes' drive time of any location in Shelby County.

- c. Applications that include non-Tennessee counties in their proposed Service Areas should provide evidence of the number of existing MRT units that service the non-Tennessee counties and the impact on MRT unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity (if that data are available).

Response: Not applicable. These units are already in service and the applicant's primary service area consists of Shelby County.

4. Economic Efficiencies. All applicants for any proposed new MRT Unit should document that lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

Response: Not applicable. This application is not for a new MRT unit, but only the change of ownership of two existing units, and thus the initiation of services by a different provider.

5. Separate Inventories for Linear Accelerators and for other MRT Units. A separate inventory shall be maintained by the HSDA for Linear Accelerators, for Proton Beam Therapy MRT Units, and, if data are available, for Linear Accelerators dedicated to SRT and/or SBRT procedures and other types of MRT Units.

Response: The linear accelerators subject to this application are in the HSDA inventory and it is anticipated that they will remain so.

6. Patient Safety and Quality of Care. The applicant shall provide evidence that any proposed MRT Unit is safe and effective for its proposed use.

- a. The United States Food and Drug Administration (FDA) must certify the proposed MRT Unit for clinical use.

Response: As the MRT Unit is already in operation, it has already been certified by the FDA for clinical use.

- b. The applicant should demonstrate that the proposed MRT Units shall be housed in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

Response: The proposed MRT Units are housed in dedicated office-based space of the West Cancer Center, which physical environment conforms to applicable federal standards and manufacturer's specifications.

- c. The applicant should demonstrate how emergencies within the MRT Unit facility will be managed in conformity with accepted medical practice. Tennessee Open Meetings Act and/or Tennessee Open Records Act.

Response: The Applicant has a crash cart for emergencies. In addition, the applicant has either a physician or a mid-level provider in the building at all times. In the unlikely event of an emergency due to anything related to the linear accelerators, the applicant would call 911 and have the patient transported to an emergency room. The closest emergency room is at Methodist LeBonheur Germantown, or the patient and/or ambulance may choose another emergency room.

- d. The applicant should establish protocols that assure that all MRT Procedures performed are medically necessary and will not unnecessarily duplicate other services.

Response: The Applicant is currently utilizing protocols that assure that all MRT procedures are medically necessary and will not unnecessarily duplicate other services.

- e. An applicant proposing to acquire any MRT Unit shall demonstrate that it meets the staffing and quality assurance requirements of the American Society of Therapeutic Radiation and Oncology (ASTRO), the American College of Radiology (ACR), the American College of Radiation Oncology (ACRO) or a similar accrediting authority such as the National Cancer Institute (CNI). Additionally, all applicants shall commit to obtain accreditation from ASTRO, ACR or a comparable accreditation authority for MRT Services within two years following initiation of the operation of the proposed MRT Unit.

Response: The MRT unit at this location meets all staffing and quality assurance requirements of the ACR and is in the process of receiving accreditation by APEX.

- f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.

Response: Depending on the emergency, the applicant anticipates transferring patients to the closest emergency room, which is Methodist-Germantown. The medical director is an active member of the staff of Methodist-Germantown.

- g. All applicants should provide evidence of any onsite simulation and treatment planning services to support the volumes they project and any impact such services may have on volumes and treatment times.

Response: The Applicant operates full simulation and treatment planning services on-site at the West Cancer Center. Such simulation and treatment planning services are provided by a radiation technician, dosimetrist and physicist personnel.

7. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

Response: The applicant will submit such data in accordance with the request of the HSDA in order to maintain the HSDA Equipment Registry.

8. In light of Rule 0720-11.01, which lists the factors concerning need on which an application may be evaluated, and Principle No. 2 in the State Health Plan, "Every citizen should have reasonable access to health care," the USDA may decide to give special consideration to an applicant:

- a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

Response: Not applicable. Shelby County is not designated as a medically underserved area.

- b. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program; or

Response: Not applicable.

- c. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

Response: The applicant already contracts with the TennCare MCOs in its service area, and participates in the Medicare program.

Comments:

1. The Office of Health Planning recognizes the need to review MRT Services standards and criteria on a frequent basis due to the evolving nature of the technology involved.
2. It is anticipated that the Tennessee Cancer Registry data, maintained by the Department of Health, will in the future become available for use by applicants to support the need for new MRT Units.

POSITRON EMISSION TOMOGRAPHY SERVICES

1. Applicants proposing a new stationary PET unit should project a minimum of at least 1,000 PET procedures in the first year of service, building to a minimum of 1,600 procedures per year by the second year of service and for every year thereafter. Providers proposing a mobile PET unit should project a minimum of at least 133 mobile PET procedures in the first year of service per day of operation per week, building to an annual minimum of 320 procedures per day of operation per week by the second year of service and for every year thereafter. The minimum number of procedures for a mobile PET unit should not exceed a total of 1600 procedures per year if the unit is operated more than five (5) days per week. The application for mobile and stationary units should include projections of demographic patterns, including analysis of applicable population-based health status factors and estimated utilization by patient clinical diagnoses category (ICD-9).

For units with a combined utility, e.g., PET/CT units, only scans involving the PET function will count towards the minimum number of procedures.

Response: PET procedure volume parameters are not applicable to PET/CT technology. The Applicant's PET/CT equipment is not deployed separately to provide PET procedures. Nonetheless, the Applicant's stationary PET/CT volumes for 2016, as reported on the HSDA equipment registry, were 1,757, which is greater than the 1600 procedures per year. The applicant projects that the number of PET/CT procedures for 2019, the first year of operation, will be 1,800, satisfying the required number. It is important to point out that PET/CT scans take longer than just PET scans, because two imaging modalities are being used at the same time. The ability to have a PET/CT for oncology patients is key to the early detection of cancer.

2. All providers applying for a proposed new PET unit should document that the proposed location is accessible to approximately 75% of the service area's population. Applications that include non-Tennessee counties in their proposed service areas should provide evidence of the number of existing PET units that service the non-Tennessee counties and the impact on PET unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity.

Response: Not applicable. The PET/CT units are already in existence.

3. All providers should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

Response: Not applicable. The equipment is in use and the services are already being provided to the patients of the West Clinic.

4. Any provider proposing a new mobile PET unit should demonstrate that it offers or has established referral agreements with providers that offer as a minimum, cancer treatment services, including radiation, medical and surgical oncology services.

Response: Not applicable.

5. A need likely exists for one additional stationary PET unit in a service area when the combined average utilization of existing PET service providers is at or above 80% of the total capacity of 2,000 procedures during the most recent twelve-month period reflected in the provider medical equipment report maintained by the USDA. The total capacity per PET unit is based upon the following formula:

Stationary Units: Eight (8) procedures/day x 250 days/year = 2,000 procedures/year

Mobile Units: Eight (8) procedures /day x 50 days/year= 400 procedures/year

The provider should demonstrate that its acquisition of an additional stationary or mobile PET unit in the service area has the means to perform at least 1,000 stationary PET procedures or 133 mobile PET procedures per day of operation per week in the first full one-year period of service operations, and at least 1,600 stationary PET procedures or 320 mobile PET procedures per day of operation per week for every year thereafter.

Response: The PET/CT units are already in use. The number of procedures performed for 2016 was 1,757, according to the HSDA Equipment Registry.

6. The applicant should provide evidence that the PET unit is safe and effective for its proposed use.
- a. The United States Food and Drug Administration (FDA) must certify the proposed PET unit for clinical use.

Response: The equipment is already in use and was certified for clinical use at the time the PET/CT was put into operation.

- b. The applicant should demonstrate that the proposed PET procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

Response: The PET procedures are being provided in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

- c. The applicant should demonstrate how emergencies within the PET unit facility will be managed in conformity with accepted medical practice.

Response: The Applicant has a crash cart for emergencies. In addition, the applicant has either a physician or a mid-level provider in the building at all times. In the unlikely event of an emergency due to anything related to the PET/CT, the applicant would call 911 and have the patient transported to an emergency room. The closest emergency room is at Methodist LeBonheur Germantown, or the patient and/or ambulance may choose another emergency room.

- d. The applicant should establish protocols that assure that all clinical PET procedures performed are medically necessary and will not unnecessarily duplicate other services.

Response: It is not necessary to establish such protocols because they are already in existence and adhered to by West Clinic. In addition, some commercial payors require pre-certification prior to the scan being performed, which also ensures that the procedures are medically necessary.

- e. The PET unit should be under the medical direction of a licensed physician. The applicant should provide documentation that attests to the nature and scope of the duties and responsibilities of the physician medical director. Clinical supervision and interpretation services must be provided by physicians who are licensed to practice medicine in the state of Tennessee and are board certified in Nuclear Medicine or Diagnostic Radiology. Licensure and oversight for the handling of medical isotopes and radiopharmaceuticals by the Tennessee Board of Pharmacy and/or the Tennessee Board of Medical Examiners—whichever is appropriate given the setting—is required. Those qualified physicians that provide interpretation services should have additional documented experience and training, credentialing, and/or board certification in the appropriate specialty and in the use and interpretation of PET procedures.

Response: Not applicable. The PET unit is under the medical direction of a licensed physician who is fully cognizant of any and all requirements as the equipment is already in use.

- f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.

Response: As an existing hospital outpatient department service, there is currently no official transfer agreement because the operator of the service and the ED are the same provider. In the unlikely event of an emergency, the applicant will continue to transfer any such emergencies to Methodist-Germantown, as the closest area hospital. The medical director of the West Cancer Center is an active member of the Methodist-Germantown medical staff.

- 7. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

Response: The applicant will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

- 8. In light of Rule 0720-4-.01 (1), which lists the factors concerning need on which an application may be evaluated, the HSDA may decide to give special consideration to an applicant:

- a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

Response: Not applicable. Shelby County is not designated as a medically underserved area.

- b. Who documents that the service area population experiences a prevalence, incidence and/or mortality from cancer, heart disease, neurological impairment or other clinical conditions applicable to PET unit services that is substantially higher than the State of Tennessee average;

Response: Based on information provided from the Tennessee Cancer Registry, Shelby County has a slightly lower incidence rate and a slightly higher mortality rate for cancer as compared to Tennessee as a whole. Shelby County is lower for lung cancer, slightly higher for female breast cancer and pancreatic cancer, and quite a bit higher for prostate cancer than the State of Tennessee.

- c. Who is a "safely net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program and/or is a comprehensive cancer diagnosis and treatment program as designated by the Tennessee Department of Health and/or the Tennessee Comprehensive Cancer Control Coalition; or

Response: Not applicable.

- d. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

Response: Not applicable. West Clinic already contracts with TennCare MCOs and Medicare.

Demographic Characteristics of Service Area by County

Demographic	Shelby County	Tennessee
Median Age – 2012-16 ACS	35.1	38.5
Age 65+ Population – 2018	125,618	1,119,024
% of Total Population	13.3%	16.5%
Age 65+ Population – 2020	133,579	1,189,428
% of Total Population	14.1%	17.3%
Median Household Income	\$46,854	\$46,574
TennCare Enrollees (4/18)	245,409	1,432,475
Percent of 2018 Population Enrolled in TennCare	26%	21.2%
Persons Below Poverty Level (2018)	196,471	1,100,169
Persons Below Poverty Level as % of Population (US Census)	21.4%	17.2%

Projected Utilization for First Eight Quarters Linear Accelerators

	Year 1	Year 2
1 st Quarter	4,812	4,825
2 nd Quarter	4,812	4,825
3 rd Quarter	4,813	4,825
4 th Quarter	4,813	4,825
Total	19,250	19,300

Projected Utilization for First Eight Quarters PET/CT

	Year 1	Year 2
1 st Quarter	450	455
2 nd Quarter	450	455
3 rd Quarter	450	455
4 th Quarter	450	455
Total	1,800	1,820

- B. Describe the relationship of this project to the applicant facility's long-range development plans, if any, and how it relates to related previously approved projects of the applicant.

Response: West Cancer Center is the premier provider of cancer diagnostic and treatment services in the region. As such, it strives to continue to provide high quality care

to its patients and is committed to doing what it can in order to continue to meet the health care needs of its service area population.

- C. Identify the proposed service area and justify the reasonableness of that proposed area. Submit a county level map for the Tennessee portion of the service area using the map on the following page, clearly marked to reflect the service area as it relates to meeting the requirements for CON criteria and standards that may apply to the project. Please include a discussion of the inclusion of counties in the border states, if applicable.
Attachment Section B - Need-C.

Response: The existing service area of the applicant for these services is Shelby County. Approximately 74% of the patients who receive PET/CT services and 80% of the patients who receive linear accelerator services are from Shelby County. Please see service area map included as Attachment Section B, Need-3.

Please complete the following tables, if applicable:

PET SERVICES

Service Area Counties	Historical Utilization-County Residents-2016	% of total procedures
County #1 Shelby	1,300	74%
Other	457	26%
Total	1,757	100%

Service Area Counties	Projected Utilization-County Residents-2019	% of total procedures
County #1 Shelby	1,332	74%
Other	468	26%
Total	1,800	100%

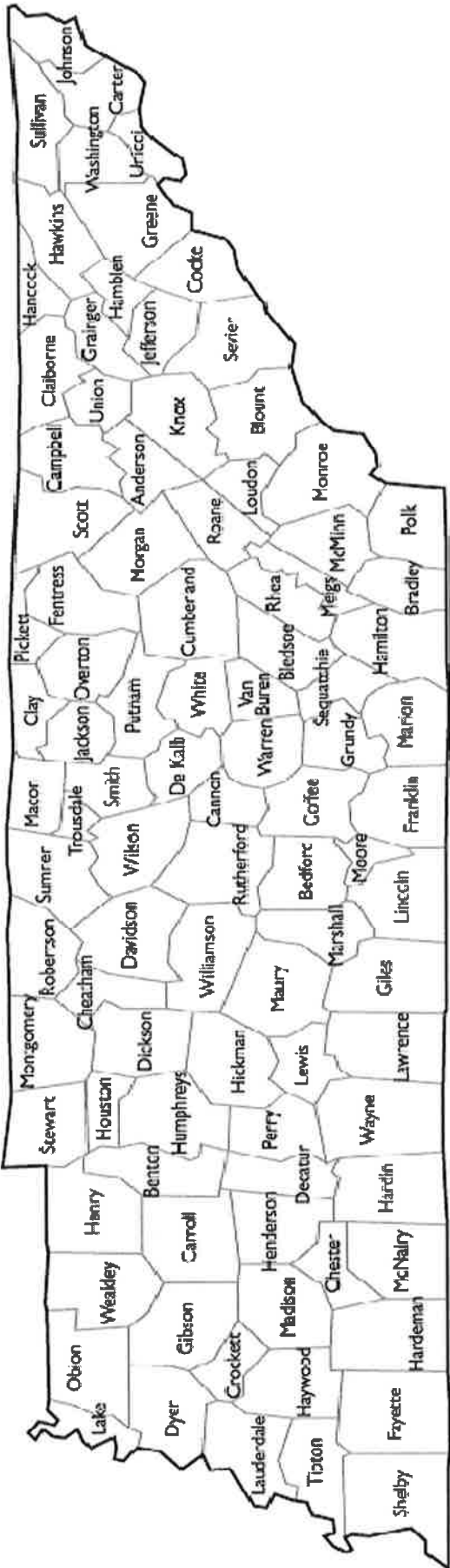
LINEAR ACCELERATOR SERVICES

Service Area Counties	Historical Utilization-County Residents-2016	% of total procedures
County #1	14,563	80%
Etc. Other	3,641	20%
Total	18,204	100%

Service Area Counties	Projected Utilization-County Residents-2019	% of total procedures
County #1 Shelby	15,400	80%
Other	3,850	20%
Total	19,250	100%

Response: The above tables show the historical and projected utilization for Shelby County, the service area of the Applicant. Any differences between 2016 and 2019 are anticipated to be minimal because these are established services.

County Level Map



- D. 1) a) Describe the demographics of the population to be served by the proposal.

Response: As can be seen in the table below, the population for Shelby County is growing at a slower rate than that for Tennessee, but the percentage of the target population as a percentage of the total population is slightly less for Shelby County than for the State of Tennessee. The Shelby County population has a younger median age, a higher percentage of persons below the poverty level, and a higher percentage of TennCare enrollees than the State of Tennessee.

- b) Using current and projected population data from the Department of Health, the most recent enrollee data from the Bureau of TennCare, and demographic information from the US Census Bureau, complete the following table and include data for each county in your proposed service area.

Projected Population Data: <http://www.tn.gov/health/article/statistics-population>

TennCare Enrollment Data: <http://www.tn.gov/tenncare/topic/enrollment-data>

Census Bureau Fact Finder: <http://factfinder.census.gov/faces/nav/jsf/pages/index.xhtml>

Demographic Variable/ Geographic Area	Department of Health/Health Statistics							Bureau of the Census				TennCare	
	Total Population- Current Year 2018	Total Population- Projected Year 2020	Total Population-% Change	*Target Population- Current Year	*Target Population- Project Year	*Target Population- % Change	Target Population Projected Year as % of Total	Median Age	Median Household Income	Person Below Poverty Level	Person Below Poverty Level as % of Total	TennCare Enrollees	TennCare Enrollees as % of Total
Shelby County	942,648	950,532	0.8%	681,105	686,899	0.8%	72.3%	35.1	\$46,854	196,471	21.4%	245,409	26%
State of TN Total	6,769,368	6,883,347	1.7%	5,077,974	5,169,308	1.8%	75.1%	38.5	\$46,574	1,100,169	17.2%	1,432,475	21.2%

* Target Population is population that project will primarily serve. For example, nursing home, home health agency, hospice agency projects typically primarily serve the Age 65+ population; projects for child and adolescent psychiatric services will serve the Population Ages 0-19. Projected Year is defined in select service-specific criteria and standards. If Projected Year is not defined, default should be four years from current year, e.g., if Current Year is 2016, then default Projected Year is 2020.

- 2) Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

Response: Overall, the Shelby County population is younger and poorer than the population of the State of Tennessee. The applicant treats all patients, regardless of payor source, income level, age, race or gender.

Demographic Characteristics of Service Area by County

Demographic	Shelby County	Tennessee
Age 65+ Population – 2018	125,618	1,119,024
% of Total Population	13.3%	16.5%
Age 65+ Population – 2020	133,579	1,189,428
% of Total Population	14.1%	17.3%
TennCare Enrollees (4/18)	245,409	1,432,475
Percent of 2018 Population Enrolled in TennCare	26%	21.2%
Persons Below Poverty Level (2018)	196,471	1,100,169
Persons Below Poverty Level as % of Population (US Census)	21.4%	17.2%

- E. Describe the existing and approved but unimplemented services of similar healthcare providers in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. List each provider and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: Admissions or discharges, patient days, average length of stay, and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc. This doesn't apply to projects that are solely relocating a service.

Response: Please see table below for utilization for Shelby County linear accelerators and PET scanners.

Shelby County Linear Accelerators Utilization

Shelby County Providers	Number of Scanners	Treatments		
		2014	2015	2016
West Cancer Center	3/2		11,009	18,204
Baptist Memorial Hospital-Memphis	2	10,590	9,968	9,064
Baptist Memorial Hospital Tipton-Bartlett	1	4,647	4,694	3,782
Methodist Healthcare-University Hospital	3/2	24,739	13,896	13,810
St. Francis Hospital	2	6,332	5,985	4,538
TOTAL	11/9	50,832	45,552	49,398
AVERAGE NUMBER/YEAR		6,354	5,061	5,489

Note: St. Jude Children's Research Hospital has been excluded because it only serves children; this project only serves adults.

Source: HSDA, Equipment Registry, Linear Accelerators - Utilization (As of 7/17/2017). Utilization for St. Francis Hospital is taken from the Joint Annual Report for Hospitals, 2016; It appears what was reported on the equipment registry was a typo.

**Shelby County
PET Scanners
Utilization**

Shelby County Providers	Number of Scanners	Treatments		
		2014	2015	2016
West Cancer Center	1	1,586	1,515	1,757
West Cancer Center-Midtown	1	855	887	962
Baptist Memorial Hospital-Memphis	1	1,053	1,141	1,118
East Memphis PET Imaging Center, LLC	1	615	551	423
TOTAL	4	4,109	4,094	4,260
AVERAGE NUMBER/YEAR		1,027	1,024	1.065

Note: St. Jude Children's Research Hospital has been excluded because it only serves children; this project Source: HSDA, Equipment Registry, PET Scanners - Utilization (As of 7/17/2017).

- F. Provide applicable utilization and/or occupancy statistics for your institution for each of the past three years and the projected annual utilization for each of the two years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology must include detailed calculations or documentation from referral sources, and identification of all assumptions.

Response: Please see the projected annual utilization for each of the two (2) years following completion of the project in the chart below.

Projected Annual Utilization

Description	2016	2017	2018 YTD	2018 Annual	Year 1	Year 2
Radiation therapy	18,041	17,859	9,776	19,252	19,250	19,300
Per lin acc (2 units)	9,021	8,930	4,888	9,626	9,625	9,650

	2016	2017	2018 YTD	2018 Annual	Year 1	Year 2
PET/CT	1,757	1,975	604	1,812	1,800	1,820

SECTION B: ECONOMIC FEASIBILITY

A. Provide the cost of the project by completing the Project Costs Chart on the following page. Justify the cost of the project.

- 1) All projects should have a project cost of at least \$15,000 (the minimum CON Filing Fee). (See Application Instructions for Filing Fee)

Response: Please see Project Costs chart.

- 2) The cost of any lease (building, land, and/or equipment) should be based on fair market value or the total amount of the lease payments over the initial term of the lease, whichever is greater. Note: This applies to all equipment leases including by procedure or "per click" arrangements. The methodology used to determine the total lease cost for a "per click" arrangement must include, at a minimum, the projected procedures, the "per click" rate and the term of the lease.

Response: West Clinic will be purchasing the building from Methodist at FMV. An appraisal has not yet been completed, so the applicant has based the cost of the building on its book value, and included the cost for the portion of the building that is used for the PET/CT and linear accelerator services including ancillary spaces such as the waiting room.

- 3) The cost for fixed and moveable equipment includes, but is not necessarily limited to, maintenance agreements covering the expected useful life of the equipment; federal, state, and local taxes and other government assessments; and installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding, which should be included under construction costs or incorporated in a facility lease.

Response: The Applicant has included the cost of the equipment when it was purchased several years ago. Although the applicant will be paying FMV for the equipment at the time of purchase, a FMV assessment has not yet been completed. Using the cost of the equipment when it was new overestimates what the current FMV is.

- 4) Complete the Square Footage Chart on page 8 and provide the documentation. Please note the Total Construction Cost reported on line 5 of the Project Cost Chart should equal the Total Construction Cost reported on the Square Footage Chart.

Response: Not applicable.

- 5) For projects that include new construction, modification, and/or renovation—**documentation must be** provided from a licensed architect or construction professional that support the estimated construction costs. Provide a letter that includes the following:

- a) A general description of the project;
- b) An estimate of the cost to construct the project;
- c) A description of the status of the site's suitability for the proposed project; and
- d) Attesting the physical environment will conform to applicable federal standards, manufacturer's specifications and licensing agencies' requirements including the AIA Guidelines for Design and Construction of Hospital and Health Care Facilities in current use by the licensing authority.

Response: Not applicable. There is no new construction, modification and/or renovation necessary for this project.

PROJECT COST CHART

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A. Construction and equipment acquired by purchase:		
1. Architectural and Engineering Fees		
2. Legal, Administrative (Excluding CON Filing Fee), Consultant Fees		\$50,000.00
3. Acquisition of Site		\$4,791,445.00
4. Preparation of Site		
5. Total Construction Costs		
6. Contingency Fund		
7. Fixed Equipment (Not included in Construction Contract)		
8. Moveable Equipment (List all equipment over \$50,000 as separate attachments)		\$6,743,706.00
9. Other (Specify) <u>Tenant Improvements</u>		
10. Pre-Opening Expenses		
B. Acquisition by gift, donation, or lease:		
1. Facility (inclusive of building and land)		
2. Building only		
3. Land only		
4. Equipment (Specify) _____		
5. Other (Specify)		
C. Financing Costs and Fees:		
1. Interim Financing		
2. Underwriting Costs		\$71,871.00
3. Reserve for One Year's Debt Service		\$291,330.00
4. Other (Specify): <u>Working Capital</u>		
D. Estimated Project Cost		
(A+B+C)		\$11,948,352.00
E. CON Filing Fee		\$68,703.02
F. Total Estimated Project Cost		
(D+E)	TOTAL	\$12,017,055.02

B. Identify the funding sources for this project.

Check the applicable item(s) below and briefly summarize how the project will be financed. ***(Documentation for the type of funding MUST be inserted at the end of the application, in the correct alpha/numeric order and identified as Attachment C, Economic Feasibility-2.)***

- ☒ 1) Commercial loan – Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;
- ☐ 2) Tax-exempt bonds – Copy of preliminary resolution or a letter from the issuing authority stating favorable initial contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;
- ☐ 3) General obligation bonds – Copy of resolution from issuing authority or minutes from the appropriate meeting;
- ☐ 4) Grants – Notification of intent form for grant application or notice of grant award;
- ☐ 5) Cash Reserves – Appropriate documentation from Chief Financial Officer of the organization providing the funding for the project and audited financial statements of the organization; and/or
- ☐ 6) Other – Identify and document funding from all other sources.

Response: The Applicant anticipates receiving a commercial loan for the funding for the project. Please see letter included as Attachment C, Economic Feasibility-2.

C. Complete Historical Data Charts on the following two pages—**Do not modify the Charts provided or submit Chart substitutions!**

Historical Data Chart represents revenue and expense information for the last *three (3)* years for which complete data is available. Provide a Chart for the total facility and Chart just for the services being presented in the proposed project, if applicable. **Only complete one chart if it suffices.**

Note that “Management Fees to Affiliates” should include management fees paid by agreement to the parent company, another subsidiary of the parent company, or a third party with common ownership as the applicant entity. “Management Fees to Non-Affiliates” should include any management fees paid by agreement to third party entities not having common ownership with the applicant.

Response: The Applicant does not have an historical data chart because the services are currently provided as an outpatient department of Methodist, which is a separate legal entity from the Applicant.

HISTORICAL DATA CHART

Not applicable.

☐ Total Facility

☐ Project Only

Give information for the last *three (3)* years for which complete data are available for the facility or agency. The fiscal year begins in (Month). **Response:** Not Applicable.

	Year	Year	Year
A. Utilization Data (Specify unit of measure, e.g., 1,000 patient days, 500 visits)			
B. Revenue from Services to Patients			
1. Inpatient Services	\$	\$	\$
2. Outpatient Services			
3. Emergency Services			
4. Other Operating Revenue (Specify) _____			
Gross Operating Revenue	\$	\$	\$
C. Deductions from Gross Operating Revenue			
1. Contractual Adjustments	\$	\$	\$
2. Provision for Charity Care			
3. Provisions for Bad Debt			
Total Deductions	\$	\$	\$
NET OPERATING REVENUE	\$	\$	\$
D. Operating Expenses			
1. Salaries and Wages			
a. Direct Patient Care			
b. Non-Patient Care			
2. Physician's Salaries and Wages			
3. Supplies			
4. Rent			
a. Paid to Affiliates			
b. Paid to Non-Affiliates			
5. Management Fees:			
a. Paid to Affiliates			
b. Paid to Non-Affiliates			
6. Other Operating Expenses			
Total Operating Expenses	\$	\$	\$
E. Earnings Before Interest, Taxes and Depreciation	\$	\$	\$
F. Non-Operating Expenses			
1. Taxes	\$	\$	\$
2. Depreciation			
3. Interest			
4. Other Non-Operating Expenses			
Total Non-Operating Expenses	\$	\$	\$
NET INCOME (LOSS)	\$	\$	\$

Chart Continues Onto Next Page

NET INCOME (LOSS)	<u>\$</u>	<u>\$</u>	<u>\$</u>
G. Other Deductions			
1. Annual Principal Debt Repayment	<u>\$</u>	<u>\$</u>	<u>\$</u>
2. Annual Capital Expenditure	<u></u>	<u></u>	<u></u>
Total Other Deductions	<u>\$</u>	<u>\$</u>	<u>\$</u>
NET BALANCE	<u>\$</u>	<u>\$</u>	<u>\$</u>
DEPRECIATION	<u>\$</u>	<u>\$</u>	<u>\$</u>
FREE CASH FLOW (Net Balance + Depreciation)	<u>\$</u>	<u>\$</u>	<u>\$</u>

- ☐ Total Facility
☐ Project Only

HISTORICAL DATA CHART-OTHER EXPENSES

<u>OTHER EXPENSES CATEGORIES</u>	<u>Year</u>	<u>Year</u>	<u>Year</u>
1.	<u>\$</u>	<u>\$</u>	<u>\$</u>
2.	<u></u>	<u></u>	<u></u>
3.	<u></u>	<u></u>	<u></u>
4.	<u></u>	<u></u>	<u></u>
5.	<u></u>	<u></u>	<u></u>
Total Other Expenses	<u>\$</u>	<u>\$</u>	<u>\$</u>

D. Complete Projected Data Charts on the following two pages – **Do not modify the Charts provided or submit Chart substitutions!**

The Projected Data Chart requests information for the two years following the completion of the proposed services that apply to the project. Please complete two Projected Data Charts. One Projected Data Chart should reflect revenue and expense projections for the ***Proposal Only*** (i.e., if the application is for additional beds, include anticipated revenue from the proposed beds only, not from all beds in the facility). The second Chart should reflect information for the total facility. **Only complete one chart if it suffices.**

Note that "Management Fees to Affiliates" should include management fees paid by agreement to the parent company, another subsidiary of the parent company, or a third party with common ownership as the applicant entity. "Management Fees to Non-Affiliates" should include any management fees paid by agreement to third party entities not having common ownership with the applicant.

Response: Please see projected data chart for the linear accelerator services and a separate chart for the PET/CT services.

**PROJECTED DATA CHART
LINEAR ACCELERATORS**

☐ Total Facility
☒ Project Only

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in January (Month).

	Year 2019	Year 2020
A. Utilization Data (Specify unit of measure, e.g., 1,000 patient days, 500 visits) Unit of Measure = MRT procedures	19,250	19,300
B. Revenue from Services to Patients		
1. Inpatient Services Not applicable	\$	\$
2. Outpatient Services Not applicable	\$	\$
3. Emergency Services Not applicable		
4. Other Operating Revenue (Specify) Technical, Medical Physics and Professional Charges	\$84,588,283	\$85,434,166
Gross Operating Revenue	\$84,588,283	\$85,434,166
C. Deductions from Gross Operating Revenue		
1. Contractual Adjustments	-\$63,483,505	-\$64,118,341
2. Provision for Charity Care	-\$1,670,619	-\$1,687,325
3. Provisions for Bad Debt	-\$1,670,619	-\$1,687,325
Total Deductions	-\$66,824,743	-\$67,492,991
NET OPERATING REVENUE	\$17,763,539	\$17,941,175
D. Operating Expenses		
1. Salaries and Wages and Benefits	\$2,606,273	\$2,684,461
a. Direct Patient Care		
b. Non-Patient Care		
2. Physician's Salaries and Wages	\$2,997,137	\$3,027,108
3. Supplies	\$142,959	\$147,248
4. Rent		
a. Paid to Affiliates		
b. Paid to Non-Affiliates		
5. Management Fees:	\$	\$
a. Paid to Affiliates		
b. Paid to Non-Affiliates		
6. Other Operating Expenses: maintenance contracts, repairs, non-med supplies/exp; overhead allocation exp.	\$4,422,596	\$4,491,833
Total Operating Expenses	\$10,168,965	\$10,350,650
E. Earnings Before Interest, Taxes and Depreciation	\$7,594,574	\$7,590,525
F. Non-Operating Expenses		
1. Taxes	\$	\$
2. Depreciation	\$500,000	\$500,000
3. Interest		
4. Other Non-Operating Expenses		
Total Non-Operating Expenses	\$500,000	\$500,000
NET INCOME (LOSS)	\$7,094,574	\$7,090,525

Chart Continues Onto Next Page

NET INCOME (LOSS)	<u>\$7,094,574</u>	<u>\$7,090,525</u>
G. Other Deductions		
1. Estimated Annual Principal Debt Repayment	<u>\$</u>	<u>\$</u>
2. Annual Capital Expenditure	<u>\$</u>	<u>\$</u>
Total Other Deductions	<u>\$</u>	<u>\$</u>
NET BALANCE	<u>\$</u>	<u>\$</u>
DEPRECIATION	<u>\$</u>	<u>\$</u>
FREE CASH FLOW (Net Balance + Depreciation)	<u>\$7,094,574</u>	<u>\$7,090,525</u>

☐ Total Facility
☒ Project Only

PROJECTED DATA CHART-OTHER EXPENSES

<u>OTHER EXPENSES CATEGORIES</u>	<u>Year 2019</u>	<u>Year 2020</u>
1. Maintenance Contracts	<u>\$800,670</u>	<u>\$800,670</u>
2. Repairs	<u>\$100,594</u>	<u>\$101,600</u>
3. Non-medical Supplies and Expenses	<u>\$349,271</u>	<u>\$385,782</u>
4. Overhead Allocation Expenses	<u>\$3,172,061</u>	<u>\$3,203,781</u>
5. Non-Medical Supplies and Expenses	<u>\$</u>	<u>\$</u>
Total Other Expenses	<u>\$4,422,596</u>	<u>\$4,491,833</u>

**PROJECTED DATA CHART
PET/CT**

☐ Total Facility
☒ Project Only

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in January (Month).

	Year 2019	Year 2020
A. Utilization Data (Specify unit of measure, e.g., 1,000 patient days, 500 visits) Unit of Measure = PET/CT procedures	1,800	1,820
B. Revenue from Services to Patients		
1. Inpatient Services Not applicable		
2. Outpatient Services Not applicable		
3. Emergency Services Not applicable		
4. Other Operating Revenue (Specify) Technical, Medical Physics and Professional Charges	\$23,315,650	\$23,548,807
Gross Operating Revenue	\$23,315,650	\$23,548,807
C. Deductions from Gross Operating Revenue		
1. Contractual Adjustments	-\$18,605,888	-\$18,791,947
2. Provision for Charity Care	-\$489,629	-\$494,525
3. Provisions for Bad Debt	-\$489,629	-\$494,525
Total Deductions	-\$19,585,146	-\$19,780,997
NET OPERATING REVENUE	\$3,730,504	\$3,767,810
D. Operating Expenses		
1. Salaries and Wages and Benefits	\$243,691	\$251,002
a. Direct Patient Care		
b. Non-Patient Care		
2. Physician's Salaries and Wages	\$530,250	\$535,553
3. Supplies	\$352,699	\$363,280
4. Rent		
a. Paid to Affiliates		
b. Paid to Non-Affiliates		
5. Management Fees:	\$	\$
a. Paid to Affiliates		
b. Paid to Non-Affiliates		
6. Other Operating Expenses: Maintenance contracts; repairs; non-medical supplies/exp., overhead allocation expenses	\$1,068,197	\$1,082,756
Total Operating Expenses	\$2,194,837	\$2,232,590
E. Earnings Before Interest, Taxes and Depreciation	\$1,535,667	\$1,535,219
F. Non-Operating Expenses		
1. Taxes	\$	\$
2. Depreciation	\$40,000	\$40,000
3. Interest		
4. Other Non-Operating Expenses		
Total Non-Operating Expenses	\$	\$
NET INCOME (LOSS)	\$1,495,667	\$1,495,219

Chart Continues Onto Next Page

NET INCOME (LOSS)	<u>\$1,495,667</u>	<u>\$1,495,219</u>
G. Other Deductions		
1. Estimated Annual Principal Debt Repayment	<u>\$</u>	<u>\$</u>
2. Annual Capital Expenditure	<u></u>	<u>\$</u>
Total Other Deductions	<u>\$</u>	<u>\$</u>
NET BALANCE	<u>\$</u>	<u>\$</u>
DEPRECIATION	<u>\$</u>	<u>\$</u>
FREE CASH FLOW (Net Balance + Depreciation)	<u>\$1,699,132</u>	<u>\$1,703,589</u>

☐ Total Facility
☒ Project Only

PROJECTED DATA CHART-OTHER EXPENSES

<u>OTHER EXPENSES CATEGORIES</u>	<u>Year 2019</u>	<u>Year 2020</u>
1. Maintenance Contracts	<u>\$157,350</u>	<u>\$157,350</u>
2. Repairs	<u>\$5,000</u>	<u>\$5,000</u>
3. Non-Medical Supplies and Expenses	<u>\$31,510</u>	<u>\$37,326</u>
4. Overhead Allocation Expenses	<u>\$874,337</u>	<u>\$883,080</u>
Total Other Expenses	<u>\$1,068,197</u>	<u>\$1,082,756</u>

- E. 1) Please identify the project's average gross charge, average deduction from operating revenue, and average net charge using information from the Projected Data Chart for Year 1 and Year 2 of the proposed project. Please complete the following table.

LINEAR ACCELERATORS (Per Procedure)

	Previous Year 2017	Current Year 2018 (annualized)	Year One 2019	Year Two 2020	% Change (Current Year to Year 2)
Gross Charge (<i>Gross Operating Revenue/Utilization Data</i>)	\$4,197.92	\$4,350.24	\$4,394.20	\$4,426.64	1.7%
Deduction from Revenue (<i>Total Deductions/Utilization Data</i>)	-\$3,140.97	-\$3,254.84	\$3,471.42	\$3,497.05	6.9%
Average Net Charge (<i>Net Operating Revenue/Utilization Data</i>)	\$1,056.97	\$1,095.40	\$922.78	\$929.59	-15.1%

PET/CT (Per Procedure)

	Previous Year 2017	Current Year 2018 (annualized)	Year One 2019	Year Two 2020	% Change (Current Year to Year 2)
Gross Charge (<i>Gross Operating Revenue/Utilization Data</i>)	\$12,537	\$12,740	\$12,953	\$12,940	1.5%
Deduction from Revenue (<i>Total Deductions/Utilization Data</i>)	\$10,030	\$10,192	\$10,880	\$10,868	6.2%
Average Net Charge (<i>Net Operating Revenue/Utilization Data</i>)	\$2,507	\$2,548	\$2,072	\$2,070	-\$18.8%

- 2) Provide the proposed charges for the project and discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the project and the impact on existing patient charges.

Response: The linear accelerator and PET/CT equipment is currently used to provide patient care services in a hospital outpatient (HOPD) point-of-service (POS) setting. Upon the approval of this project and the implementation of the services as a physician office POS, the average net charge is expected to be approximately 16% less for linear accelerator services and 19% less for PET/CT services. This is based on the anticipated lower reimbursement rate to physician offices for the same services. Thus, it is expected that the cost to patients and payors will be less as a result of the approval of this project.

3. Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the

project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

Response:

- F. 1) Discuss how projected utilization rates will be sufficient to support the financial performance. Indicate when the project's financial breakeven is expected and demonstrate the availability of sufficient cash flow until financial viability is achieved. Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For all projects, provide financial information for the corporation, partnership, or principal parties that will be a source of funding for the project. Copies must be inserted at the end of the application, in the correct alpha-numeric order and labeled as Attachment C, Economic Feasibility. **NOTE: Publicly held entities only need to reference their SEC filings.**

Response: . The volume utilization of both the linear accelerators and the PET/CT are above HSDA volume guidelines. The project will be above breakeven and profitable from its inception.

- 2) Net Operating Margin Ratio – Demonstrates how much revenue is left over after all the variable or operating costs have been paid. The formula for this ratio is: (Earnings before interest, Taxes, and Depreciation/Net Operating Revenue).

Utilizing information from the Historical and Projected Data Charts please report the net operating margin ratio trends in the following table:

Year	2nd Year previous to Current Year	1st Year previous to Current Year	Current Year	Projected Year 1	Projected Year 2
Net Operating Margin Ratio	N/A	N/A	N/A	1:1	1:1

- 3) Capitalization Ratio (Long-term debt to capitalization) – Measures the proportion of debt financing in a business's permanent (Long-term) financing mix. This ratio best measures a business's true capital structure because it is not affected by short-term financing decisions. The formula for this ratio is: (Long-term debt/(Long-term debt/Total Equity (Net assets)) x 100).

For the entity (applicant and/or parent company) that is funding the proposed project please provide the capitalization ratio using the most recent year available from the funding entity's audited balance sheet, if applicable. The Capitalization Ratios are not expected from outside the company lenders that provide funding.

Response:

- G. Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid and medically indigent patients will be served by the project. Additionally, report the estimated gross operating revenue dollar amount and percentage of projected gross operating revenue anticipated by payor classification for the first year of the project by completing the table below.

Response: Please see the payor mix for both the linear accelerators and the PET/CT. As can be seen in the tables below, the payor mix is slightly different for the linear accelerators and the PET/CT.

Linear Accelerators

Applicant's Projected Payor Mix, Year 1

Payor Source	Projected Gross Operating Revenue	As a % of total
Medicare/Medicare Managed Care	\$39,333,552	46.50%
TennCare/Medicaid	\$ 3,806,473	4.50%
Commercial/Other Managed Care	\$38,910,610	46.00%
Self-Pay	\$1,268,824	1.50%
Charity Care	\$634,412	.75%
Other (Specify): Bad Debt	\$634,412	.75%
Total	\$84,588,283	100.00%

PET/CT

Applicant's Projected Payor Mix, Year 1

Payor Source	Projected Gross Operating Revenue	As a % of total
Medicare/Medicare Managed Care	\$12,613,767	54.10%
TennCare/Medicaid	\$1,562,149	6.70%
Commercial/Other Managed Care	\$7,973,952	34.20%
Self-Pay	\$582,891	2.50%
Charity Care	\$291,446	1.25%
Other (Specify): Bad Debt	\$291,446	1.25%
Total	\$23,315,650	100.00%

- H. Provide the projected staffing for the project in Year 1 and compare to the current staffing for the most recent 12-month period, as appropriate. This can be reported using full-time equivalent (FTEs) positions for these positions. Additionally, please identify projected salary amounts by position classifications and compare the clinical staff salaries to prevailing wage patterns in the proposed service area as published by the Department of Labor & Workforce Development and/or other documented sources.

Response: Please see projected staffing and wages below.

Germantown Linear Accelerator:

Position Classification	Existing FTEs (enter year)	Projected FTEs Year 1	Average Wage (Contractual Rate)	Area Wide/Statewide Average Wage
A. Direct Patient Care Positions				
<i>Position 1: Medical Physicists</i>	2	3	\$150,800	\$132,290
<i>Position 2 Dosimetrist</i>	4	4	\$104,000	\$102,752
<i>Position 3 -Quality Assurance Specialists</i>	1	1	\$62,400	\$54,740
<i>Position 4: Nurses</i>	3	4	\$67,600	\$59,080
<i>Position 5: Therapists</i>	8	8	\$72,800	\$51,960
Total Direct Patient Care Positions	18	20		

B. Non-Patient Care Positions				
<i>Position 1: Director</i>	1	1	\$107,120	\$87,960
<i>Position 2: Coordinator.</i>	1	1	\$41,600	\$30,400
<i>Position 3: Front Desk Coordinator</i>	2	3	\$36,400	\$30,400
Total Non-Patient Care Positions	4	5		
Total Employees (A+B)	22	25		
C. Contractual Staff				
Total Staff (A+B+C)	22	25		

Germantown PET:

Position Classification	Existing FTEs (enter year)	Projected FTEs Year 1	Average Wage (Contractual Rate)	Area Wide/Statewide Average Wage
A. Direct Patient Care Positions				
<i>Position 1: Nuclear Medicine Tech</i>	3	3	\$65,520	\$65,530
<i>Position 2</i>				
<i>Position 3 -</i>				
Total Direct Patient Care Positions				

B. Non-Patient Care Positions				
<i>Position 1:</i>	0	0	0	
<i>Position 2:</i>	0	0	0	
<i>Position 3:</i>	0	0	0	
Total Non-Patient Care Positions	0	0	0	
Total Employees (A+B)	3	3		
C. Contractual Staff				
Total Staff (A+B+C)	3	3		

I. Describe all alternatives to this project which were considered and discuss the advantages and disadvantages of each alternative including but not limited to:

- 1) Discuss the availability of less costly, more effective and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, justify why not, including reasons as to why they were rejected.

Response: There are no less costly, more effective and/or more efficient alternative methods of providing the benefits intended by the proposal. These services are already highly utilized by the patients of the West Clinic. It is the applicant's understanding that only one other scanner in the county is a PET/CT, and it is located at Baptist. The benefits of being able to offer PET/CT for cancer patients are numerous, and it is generally considered the standard of care. PET/CT technology integrates the molecular-level diagnostic capabilities of positron emission tomography (PET) with computed tomography (CT) to produce anatomic views, a practice known as image fusion or co-registration. These views allow clinical information from two different exams to be correlated and interpreted on one image, leading to more precise information and accurate diagnoses. PET/CT is prevalent in diagnosing and monitoring progression/regression of cancer.

The integration of these technologies is key to both the early detection of cancer, as well as to the treatment plan to follow. PET/CT scans generally take longer than PET scans because you are using two imaging modalities at one time, rather than just one. The linear accelerators are then used to provide treatment for the identified cancer.

- 2) Document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements.

Response: Not applicable. This project does not involve new construction.

SECTION B: CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

- A. List all existing health care providers (i.e., hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, that may directly or indirectly apply to the project, such as, transfer agreements, contractual agreements for health services.

Response:

- B. Describe the effects of competition and/or duplication of the proposal on the health care system, including the impact to consumers and existing providers in the service area. Discuss any instances of competition and/or duplication arising from your proposal including a description of the effect the proposal will have on the utilization rates of existing providers in the service area of the project.

A. Positive Effects

Response: The approval of this project will have only positive effects on the existing health care system and area providers. The approval will transfer ownership of existing equipment from Methodist to The West Clinic, and therefore the provision of the services from a HOPD setting to a physician practice setting. As previously stated, this change has the effect of decreasing costs to both payers and patients as the reimbursement to a physician provider is less than that for a HOPD.

B. Negative Effects

Response: There are no negative effects or duplication of services as a result of this project, and its approval will have no effect on any existing providers in the service area because both the PET/CT and linear accelerator services are existing services. In addition, to the applicant's knowledge, the only other PET/CT scanner in the service area is owned and operated by Baptist. A negative effect will occur if the project is not approved because patient will not be allowed to receive these necessary services.

- C. 1) Discuss the availability of and accessibility to human resources required by the proposal, including clinical leadership and adequate professional staff, as per the State of Tennessee licensing requirements and/or requirements of accrediting agencies, such as the Joint Commission and Commission on Accreditation of Rehabilitation Facilities.

Response: Because these services are already provided, the Applicant already has the necessary clinical leadership and adequate professional staff to provide these important services. Certain of the professional staff are currently employed by Methodist and with the approval and implementation of this project, the Applicant will hire those staff to continue to operate the existing services.

- 2) Verify that the applicant has reviewed and understands all licensing and/or certification as required by the State of Tennessee and/or accrediting agencies such as the Joint Commission for medical/clinical staff. These include, without limitation, regulations concerning clinical leadership, physician supervision, quality assurance policies and programs, utilization review policies and programs, record keeping, clinical staffing requirements, and staff education.

Response: The Applicant has reviewed and understands all licensing and/or certification requirements of the State as well as the accrediting agencies pursuant to which the West Cancer Center has already received accreditation. The West Cancer Center has accreditations and affiliations from the National Comprehensive Cancer Network, the NCQA, the Commission on Cancer, the Foundation for the Accreditation of Cellular Therapy, Caris Life Sciences (designated as a Center of Excellence), the National Accreditation Program for Breast Centers, and the American Society of Clinical Oncology's Quality Oncology Practice Initiative.

- 3) Discuss the applicant's participation in the training of students in the areas of medicine, nursing, social work, etc. (e.g., internships, residencies, etc.).

Response: The Applicant participates in a radiation residency program through UT.

- D. Identify the type of licensure and certification requirements applicable and verify the applicant has reviewed and understands them. Discuss any additional requirements, if applicable. Provide the name of the entity from which the applicant has received or will receive licensure, certification, and/or accreditation.

Licensure:

Response: Not applicable. This project is not required to be licensed.

Certification Type (e.g. Medicare SNF, Medicare LTAC, etc.):

Response: The applicant will be Medicare certified.

Accreditation (i.e., Joint Commission, CARF, etc.):

Response: The West Cancer Center is currently accredited by ACR, and it anticipates that it will continue to be so accredited, even after transfer of ownership of the equipment to the West Clinic.

- 1) If an existing institution, describe the current standing with any licensing, certifying, or accrediting agency. Provide a copy of the current license of the facility and accreditation designation.

Response: Not applicable. The Applicant is not an institution.

- 2) For existing providers, please provide a copy of the most recent statement of deficiencies/plan of correction and document that all deficiencies/findings have been corrected by providing a letter from the appropriate agency.

Response: Not applicable. The Applicant is not an existing provider that is subject to licensure surveys.

- 3) Document and explain inspections within the last three survey cycles which have resulted in any of the following state, federal, or accrediting body actions: suspension of admissions, civil monetary penalties, notice of 23-day or 90-day termination proceedings from Medicare/Medicaid/TennCare, revocation/denial of accreditation, or other similar actions.

Response: Not applicable.

- a) Discuss what measures the applicant has or will put in place to avoid similar findings in the future.

Response: Not applicable.

E. Respond to all of the following and for such occurrences, identify, explain and provide documentation:

- 1) Has any of the following:

- a) Any person(s) or entity with more than 5% ownership (direct or indirect) in the applicant (to include any entity in the chain of ownership for applicant);

Response: No.

- b) Any entity in which any person(s) or entity with more than 5% ownership (direct or indirect) in the applicant (to include any entity in the chain of ownership for applicant) has an ownership interest of more than 5%; and/or

Response: No.

- c) Any physician or other provider of health care, or administrator employed by any entity in which any person(s) or entity with more than 5% ownership in the applicant (to include any entity in the chain of ownership for applicant) has an ownership interest of more than 5%.

Response: No.

- 2) Been subjected to any of the following:

- a) Final Order or Judgment in a state licensure action;

Response: No.

- b) Criminal fines in cases involving a Federal or State health care offense;

Response: No.

- c) Civil monetary penalties in cases involving a Federal or State health care offense;

Response: No.

- d) Administrative monetary penalties in cases involving a Federal or State health care offense;

Response: No.

- e) Agreement to pay civil or administrative monetary penalties to the federal government or any state in cases involving claims related to the provision of health care items and services; and/or

Response: No.

- f) Suspension or termination of participation in Medicare or Medicaid/TennCare programs.

Response: No.

- g) Is presently subject of/to an investigation, regulatory action, or party in any civil or criminal action of which you are aware.

Response: No.

- h) Is presently subject to a corporate integrity agreement.

Response: No.

F. Outstanding Projects:

- 1) Complete the following chart by entering information for each applicable outstanding CON by applicant or share common ownership; and

<u>Outstanding Projects</u>					
<u>CON Number</u>	<u>Project Name</u>	<u>Date Approved</u>	<u>*Annual Progress Report(s)</u>		<u>Expiration Date</u>
			<u>Due Date</u>	<u>Date Filed</u>	

*Annual Progress Reports – HSDA Rules require that an Annual Progress Report (APR) be submitted each year. The APR is due annually until the Final Project Report (FPR) is submitted (FPR is due within 90 ninety days of the completion

and/or implementation of the project). Brief progress status updates are requested as needed. The project remains outstanding until the FPR is received.

Response: Not applicable.

- 2) Provide a brief description of the current progress, and status of each applicable outstanding CON.

Response: Not applicable.

G. Equipment Registry-For the applicant and all entities in common ownership with the applicant.

- 1) Do you own, lease, operate, and/or contract with a mobile vendor for a Computed Tomography scanner (CT), Linear Accelerator, Magnetic Resonance Imaging (MRI), and/or Positron Emission Tomographer (PET)? _____

Response: No. The Applicant does not currently own, lease, operate and/or contract with a mobile vendor for any of the above-referenced services.

- 2) If yes, have you submitted their registration to HSDA? If you have, what was the date of submission?

Response: Not applicable.

- 3) If yes, have you submitted your utilization to Health Services and Development Agency? If you have, what was the date of submission?

Response: Not applicable. The Applicant is not currently providing these services.

SECTION B: QUALITY MEASURES

Please verify that the applicant will report annually using forms prescribed by the Agency concerning continued need and appropriate quality measures as determined by the Agency pertaining to the certificate of need, if approved.

Response: The applicant will report annually on measures and forms as prescribed by the Agency, pertaining to this CON if approved.

SECTION C: STATE HEALTH PLAN QUESTIONS

T.C.A. §68-11-1625 requires the Tennessee Department of Health's Division of Health Planning to develop and annually update the State Health Plan (found at <http://www.tn.gov/health/topic/health-planning>). The State Health Plan guides the State in the development of health care programs and policies and in the allocation of health care resources in the State, including the Certificate of Need program. The 5 Principles for Achieving Better Health are from the State Health Plan's framework and inform the Certificate of Need program and its standards and criteria.

Discuss how the proposed project will relate to the 5 Principles for Achieving Better Health found in the State Health Plan.

- A. The purpose of the State Health Plan is to improve the health of the people of Tennessee.

Response: The benefits of being able to offer PET/CT for cancer patients are numerous, and it is generally considered the standard of care. PET/CT technology integrates the molecular-level diagnostic capabilities of positron emission tomography (PET) with computed tomography (CT) to produce anatomic views, a practice known as image fusion or co-registration. These views allow clinical information from two different exams to be correlated and interpreted on one image, leading to more precise information and accurate diagnoses. PET/CT is prevalent in diagnosing and monitoring progression/regression of cancer.

The integration of these technologies is key to both the early detection of cancer, as well as to the treatment plan to follow. The linear accelerators are then used to provide treatment for the identified cancer.

West Cancer Center has clearly demonstrated through the years that it improves the health of the people of Tennessee for oncology services.

- B. People in Tennessee should have access to health care and the conditions to achieve optimal health.

Response: The provision of these services by The West Cancer Center enables Tennesseans in Shelby County and the surrounding areas, convenient access to vital health care services in the diagnosis and treatment of cancer.

- C. Health resources in Tennessee, including health care, should be developed to address the health of people in Tennessee while encouraging economic efficiencies.

Response: West Cancer Center is the region's comprehensive leader in adult cancer care and research, delivering a complete continuum of care to more than 30,000 individuals each year. A multidisciplinary team approach coupled with a full-spectrum of care and support services ensures that its patients are receiving the most innovative – and comprehensive – care available. The approval of this project will result in continuing to provide the same services to the existing patient population, while at the same time reducing costs to the payors and the patients because the reimbursement for these services provided in a physician office place of service is less than when they are provided in a hospital outpatient department.

- D. People in Tennessee should have confidence that the quality of health care is continually monitored and standards are adhered to by providers.

Response: The West Clinic monitors the services it provides to ensure high quality care is provided and ensures that the standards it has set are met by the West Cancer Center.

- E. The state should support the development, recruitment, and retention of a sufficient and quality health workforce.

Response: It is not necessary for the applicant to develop or recruit the quality workforce that is necessary to provide these services, but it does anticipate hiring those employees currently providing the services from Methodist and working hard to retain them.

PROOF OF PUBLICATION

Attach the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit from the newspaper that includes a copy of the publication as proof of the publication of the letter of intent.

Response: Please see attached proof of publication which occurred in The Commercial Appeal on Friday, August 10, 2018.

NOTIFICATION REQUIREMENTS

(Applies only to Nonresidential Substitution-Based Treatment Centers for Opiate Addiction)

Note that T.C.A. §68-11-1607(c)(9)(A) states that "...Within ten (10) days of the filing of an application for a nonresidential substitution-based treatment center for opiate addiction with the agency, the applicant shall send a notice to the county mayor of the county in which the facility is proposed to be located, the state representative and senator representing the house district and senate district in which the facility is proposed to be located, and to the mayor of the municipality, if the facility is proposed to be located within the corporate boundaries of a municipality, by certified mail, return receipt requested, informing such officials that an application for a nonresidential substitution-based treatment center for opiate addiction has been filed with the agency by the applicant."

Failure to provide the notifications described above within the required statutory timeframe will result in the voiding of the CON application.

Please provide documentation of these notifications.

DEVELOPMENT SCHEDULE

T.C.A. §68-11-1609(c) provides that a Certificate of Need is valid for a period not to exceed three (3) years (for hospital projects) or two (2) years (for all other projects) from the date of its issuance and after such time shall expire; provided, that the Agency may, in granting the Certificate of Need, allow longer periods of validity for Certificates of Need for good cause shown. Subsequent to granting the Certificate of Need, the Agency may extend a Certificate of Need for a period upon application and good cause shown, accompanied by a non-refundable reasonable filing fee, as prescribed by rule. A Certificate of Need which has been extended shall expire at the end of the extended time period. The decision whether to grant such an extension is within the sole discretion of the Agency, and is not subject to review, reconsideration, or appeal.

- 1. Complete the Project Completion Forecast Chart on the next page. If the project will be completed in multiple phases, please identify the anticipated completion date for each phase.**
- 2. If the response to the preceding question *indicates that the applicant does not anticipate completing the project within the period of validity as defined in the preceding paragraph*, please state below any request for an extended schedule and document the "good cause" for such an extension.**

PROJECT COMPLETION FORECAST CHART

Assuming the Certificate of Need (CON) approval becomes the final HSDA action on the date listed in Item 1. below, indicate the number of days from the HSDA decision date to each phase of the completion forecast.

<u>Phase</u>	<u>Days Required</u>	<u>Anticipated Date [Month/Year]</u>
1. Initial HSDA decision date		10/2018
2. Architectural and engineering contract signed		
3. Construction documents approved by the Tennessee Department of Health		
4. Construction contract signed		
5. Building permit secured		
6. Site preparation completed		
7. Building construction commenced		
8. Construction 40% complete		
9. Construction 80% complete		
10. Construction 100% complete (approved for occupancy		
11. *Issuance of License		
12. *Issuance of Service	70 days	1/2019
13. Final Architectural Certification of Payment	N/A	N/A
14. Final Project Report Form submitted (Form HR0055)	130 days	3/2019

*For projects that **DO NOT** involve construction or renovation, complete Items 11 & 12 only.

NOTE: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date

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AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

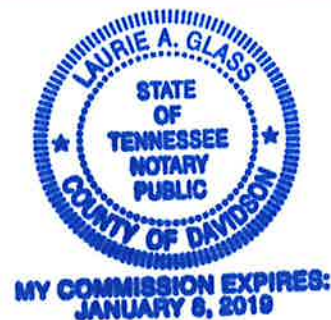
Kim H. Looney, being first duly sworn, says that he/she is the applicant named in this application or his/her/its lawful agent, that this project will be completed in accordance with the application, that the applicant has read the directions to this application, the Rules of the Health Services and Development Agency, and T.C.A. § 68-11-1601, *et seq.*, and that the responses to this application or any other questions deemed appropriate by the Health Services and Development Agency are true and complete.

Kim H. Looney
SIGNATURE/TITLE

Sworn to and subscribed before me this 15th day of August, 2018, a Notary Public in and for the County/State of Tennessee.

Laurie A. Glass
NOTARY PUBLIC

My commission expires, January 8, 2019.



Attachment A-4

Corporate Documents



Tre Hargett
Secretary of State

Division of Business Services
Department of State
State of Tennessee
312 Rosa L. Parks AVE, 6th FL
Nashville, TN 37243-1102

WALLER LANSDEN DORTCH
STE 2700
511 UNION ST
NASHVILLE, TN 37219-1791

Request Type: Certified Copies
Request #: 286114

Issuance Date: 08/14/2018
Copies Requested: 1

Document Receipt

Receipt #: 004241061

Filing Fee: \$20.00

Payment-Check/MO - WALLER LANSDEN DORTCH, NASHVILLE, TN

\$20.00

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that **THE WEST CLINIC, P.C.**, Control # 263666 was formed or qualified to do business in the State of Tennessee on 03/11/1993. THE WEST CLINIC, P.C. has a home jurisdiction of TENNESSEE and is currently in an Active status. The attached documents are true and correct copies and were filed in this office on the date(s) indicated below.


Tre Hargett
Secretary of State

Processed By: Michelle Holloway

The attached document(s) was/were filed in this office on the date(s) indicated below:

<u>Reference #</u>	<u>Date Filed</u>	<u>Filing Description</u>
2659-1307	03/11/1993	Initial Filing
2686-2170	04/28/1993	Articles of Amendment
2819-0753	03/24/1994	CMS Annual Report Update
3202-3331	08/09/1996	Articles of Amendment
3852-0712	03/14/2000	1999 Annual Report (Due 04/01/2000)
4073-1736	12/19/2000	Merger
4144-1708	03/12/2001	Assumed Name
4148-0063	03/15/2001	2000 Annual Report (Due 04/01/2001)
4459-2217	03/26/2002	2001 Annual Report (Due 04/01/2002)
4765-1372	03/25/2003	2002 Annual Report (Due 04/01/2003)
5093-0496	03/31/2004	2003 Annual Report (Due 04/01/2004)
5427-0575	04/01/2005	2004 Annual Report (Due 04/01/2005)
5678-0682	02/06/2006	Assumed Name Renewal
5747-2479	03/31/2006	2005 Annual Report (Due 04/01/2006)

The attached document(s) was/were filed in this office on the date(s) indicated below:

Reference #	Date Filed	Filing Description
5900-2134	12/12/2006	Articles of Amendment
5907-0443	12/28/2006	Merger
6012-0980	03/30/2007	2006 Annual Report (Due 04/01/2007)
6080-0070	06/26/2007	Assumed Name
6085-2206	07/05/2007	Assumed Name
6261-2542	03/26/2008	2007 Annual Report (Due 04/01/2008)
6479-2015	03/18/2009	2008 Annual Report (Due 04/01/2009)
A0012-2323	03/24/2010	2009 Annual Report (Due 04/01/2010)
A0063-2526	03/24/2011	2010 Annual Report (Due 04/01/2011)
A0111-0277	03/22/2012	2011 Annual Report (Due 04/01/2012)
7050-2792	05/02/2012	Assumed Name Cancellation
7109-2003	10/29/2012	Registered Agent Change (by Entity)
A0161-1390	03/13/2013	2012 Annual Report (Due 04/01/2013)
A0226-2592	03/26/2014	2013 Annual Report (Due 04/01/2014)
B0065-6669	03/11/2015	2014 Annual Report (Due 04/01/2015)
B0133-1340	08/10/2015	Assumed Name
B0211-4308	03/08/2016	2015 Annual Report (Due 04/01/2016)
B0359-4193	03/08/2017	2016 Annual Report (Due 04/01/2017)
B0515-7913	03/14/2018	2017 Annual Report (Due 04/01/2018)

CHARTER

OF

W.T.S.W., P.C.

SECRETARY OF STATE

The undersigned, acting as the incorporator under the Tennessee Business Corporation Act, adopts the following charter for such corporation:

1. The name of the corporation is W.T.S.W., P.C.
2. The corporation is authorized to issue One Thousand (1,000) shares of common stock, \$.01 par value per share, which shares collectively shall have unlimited voting rights and the right to receive the net assets of the corporation upon dissolution.
3. The street address and zip code of the corporation's initial registered office is:

1775 Moriah Woods Blvd.
 Suite 5
 Memphis, Tennessee 38117
4. The corporation's initial registered office is located in Shelby County, Tennessee.
5. The name of the corporation's initial registered agent at that office is Kurt W. Tauer, M.D.
6. The name, address and zip code of the incorporator is:

Kurt W. Tauer, M.D.
 1775 Moriah Woods Blvd.
 Suite 5
 Memphis, Tennessee 38117
7. The street address and zip code of the principal office of the corporation is:

1775 Moriah Woods Blvd.
 Suite 5
 Memphis, Tennessee 38117
8. The corporation is for profit.
9. The corporation is organized for the purpose of engaging in the practice of medicine and all necessary activities related thereto.
10. The corporation elects to be governed by the provisions of the Tennessee Professional Corporation Act, T.C.A. 48-3-401, et seq.
11. A director of the corporation shall not be personally liable to the corporation or its shareholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the corporation or its shareholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, or (iii) for unlawful distributions under Section 48-18-304 of the Tennessee Business Corporation Act. If the Tennessee Business Corporation Act is amended after the filing of this charter to authorize corporate action further eliminating or limiting the personal liability of the directors, then the liability of a director of the corporation shall be eliminated or limited to the fullest extent permitted by the Tennessee Business Corporation Act, as so amended.

Any repeal or modification of the foregoing paragraph by the shareholders of the corporation shall not adversely affect any right or protection of a director of the corporation existing at the time of such repeal or modification.

SECRETARY OF STATE

12. The names and address of the individuals who shall constitute the corporation's initial board of directors are:

William H. West, M.D.
1775 Moriah Woods Blvd.
Suite 5
Memphis, Tennessee 38117

Kurt W. Tauer, M.D.
1775 Moriah Woods Blvd.
Suite 5
Memphis, Tennessee 38117

Lee S. Schwartzberg, M.D.
1775 Moriah Woods Blvd.
Suite 5
Memphis, Tennessee 38117

Alva B. Weir, III, M.D.
1775 Moriah Woods Blvd.
Suite 5
Memphis, Tennessee 38117

DATED: 7 24-83


KURT W. TAUER, M.D.

2686 2170

ARTICLES OF AMENDMENT TO THE CHARTER

OF

W.T.S.W., P.C.

CHANGING THE CORPORATE NAME

TO THE SECRETARY OF STATE OF THE STATE OF TENNESSEE:

Pursuant to the provisions of Section 48-3-406 of the Tennessee Business Corporation Act, the undersigned corporation adopts the following Articles of Amendment to its Charter:

1. The name of the corporation is: W.T.S.W., P.C.
2. The amendment adopted is:
Paragraph 1 of the Charter is deleted and the following is inserted:
 1. The name of the corporation is The West Clinic, P.C.
3. The amendment was duly adopted at a meeting of the directors on March 12, 1993.
4. The amendment is to be effective when these Articles are filed by the Secretary of State.

Dated: 4/26/93

W.T.S.W., P.C.,
a Tennessee Professional Corporation

By: [Signature]
President



**CORPORATION ANNUAL REPORT
STATE OF TENNESSEE
SECRETARY OF STATE
SUITE 1800, JAMES K. POLK BUILDING
NASHVILLE, TN 37243-0306**

12-13-11-12 11-15-13

FILING FEE - \$10.00; PRIVILEGE TAX - \$10.00; TOTAL AMOUNT DUE \$20.00

CURRENT FISCAL YEAR CLOSING MONTH

03

IF DIFFERENT,

CORRECT MONTH IS

DECEMBER

THIS REPORT IS DUE ON OR BEFORE

07/01/94

(1) SECRETARY OF STATE CONTROL NUMBER

0263666

OR FEDERAL EMPLOYER IDENTIFICATION NUMBER

62-1526296

(2A) NAME AND MAILING ADDRESS OF CORPORATION:

THE WEST CLINIC, P.C.
SUITE 5, 1775 MORIAH
WOODS BLVD
MEMPHIS, TN 38117

(2B) STATE OR COUNTRY OF INCORPORATION

TENNESSEE

(2C) ADD OR CHANGE MAILING ADDRESS:

D 03/11/1993 FOR PROFIT

(3) A. PRINCIPAL ADDRESS INCLUDING CITY, STATE, ZIP CODE:

SUITE 5, 1775 MORIAH, WOODS BLVD, MEMPHIS, TN 38117

B. CHANGE OF PRINCIPAL ADDRESS:

STREET

CITY

STATE

ZIP CODE + 4

**** BLOCKS 4A AND 4B MUST BE COMPLETED OR THE ANNUAL REPORT WILL BE RETURNED ****

(4) A. NAME AND BUSINESS ADDRESS, INCLUDING ZIP CODE, OF THE PRESIDENT, SECRETARY AND OTHER PRINCIPAL OFFICERS.
(ATTACH ADDITIONAL SHEET IF NECESSARY.)

TITLE	NAME	BUSINESS ADDRESS	CITY, STATE, ZIP CODE + 4
PRESIDENT	WILLIAM H. WEST, MD	1775 MORIAH WOODS #5	MEMPHIS TN 38117
SECRETARY	LEE S. SCHWARTZBERG, MD	1775 MORIAH WOODS #5	MEMPHIS TN 38117
V-PRES	ALVA B. WEIR, III, MD	1775 MORIAH WOODS #5	MEMPHIS TN 38117
V-PRES	KURT W. TAUER, MD	1775 MORIAH WOODS #5	MEMPHIS TN 38117

B. BOARD OF DIRECTORS (NAMES, BUSINESS ADDRESS INCLUDING ZIP CODE). (ATTACH ADDITIONAL SHEET IF NECESSARY.)

☒ SAME AS ABOVE

☐ NONE

OR LIST BELOW:

NAME

BUSINESS ADDRESS

CITY, STATE, ZIP CODE + 4

(5) A. NAME OF REGISTERED AGENT AS APPEARS ON SECRETARY OF STATE RECORDS:

KURT W. TAUER, M.D.

B. REGISTERED ADDRESS AS APPEARS ON SECRETARY OF STATE RECORDS:

SUITE 5, 1775 MORIAH, WOODS BLVD, MEMPHIS, TN 38117

(6) INDICATE BELOW ANY CHANGES TO THE REGISTERED AGENT NAME AND/OR REGISTERED OFFICE.

(BLOCK 5A AND/OR 5B.) THERE IS AN ADDITIONAL \$10.00 FILING FEE AND \$10.00 PRIVILEGE TAX FOR A TOTAL OF \$20.00 REQUIRED FOR CHANGES MADE TO THIS INFORMATION.

A. CHANGE OF REGISTERED AGENT:

B. CHANGE OF REGISTERED OFFICE:

STREET

CITY

STATE

ZIP CODE + 4

COUNTY

(7) A. THIS BOX APPLIES ONLY TO NONPROFIT CORPORATIONS. OUR RECORDS REFLECT THAT YOUR NONPROFIT CORPORATION IS A PUBLIC BENEFIT OR A MUTUAL BENEFIT CORPORATION AS INDICATED BELOW:

IF BLANK OR CHANGE, PLEASE CHECK APPROPRIATE BOX:

☐ PUBLIC

☐ MUTUAL

B. IF A TENNESSEE RELIGIOUS CORPORATION, PLEASE CHECK BOX UNLESS OTHERWISE INDICATED.

☐ RELIGIOUS

(8) SIGNATURE

(9) DATE

3/21/94

(10) TYPE/PRINT NAME OF SIGNER:

KURT W. TAUER MD

(11) TITLE OF SIGNER

VICE PRESIDENT

**** THIS REPORT MUST BE DATED AND SIGNED ****

ARTICLES OF AMENDMENT TO THE CHARTER

of

THE WEST CLINIC, P.C.

CHANGING THE NUMBER OF SHARES AUTHORIZED TO BE ISSUED

Pursuant to the provisions of Section 48-20-106 of the Tennessee Business Corporation Act, the undersigned corporation adopts the following articles of amendment to its charter:

1. The name of the corporation is THE WEST CLINIC, P.C..
2. The text of the amendment adopted is as follows:

Article 2 shall be amended to read as follows:

The Corporation is authorized to issue Two Thousand (2,000) shares of common stock, \$.01 par value per share, which shares collectively shall have unlimited voting rights and the right to receive the net assets of the Corporation upon dissolution.

3. The amendment was adopted on January 31, 1995.
4. The amendment was duly adopted by the shareholders.

Dated: January 31, 1995.

THE WEST CLINIC, P.C.



Lee S. Schwartzberg, Secretary

WRITTEN CONSENT TO MERGE

W.T.S., P.C.

INTO

THE WEST CLINIC, P.C.

The undersigned being the Directors of W.T.S., P.C. and the Directors of THE WEST CLINIC, P.C., hereby adopt the following resolution by this written consent, pursuant to Section 48-18-202 of the Tennessee Business Corporation Act and Section 48-101-622 of the Tennessee Professional Corporation Act:

RESOLVED, that by the Agreement and Plan of Merger attached hereto and incorporated herein by reference, W.T.S., P.C. shall be merged into THE WEST CLINIC, P.C., such merger to take effect on the effective date of the Articles of Merger and Agreement and plan of Merger.

IN WITNESS WHEREOF, I have executed this Consent this the 1st day of January, 2000.

W.T.S., P.C.,
A Tennessee Professional Corporation

By: Lee Schwartzberg
Lee Schwartzberg, M.D., Secretary

DIRECTORS OF W.T.S., P.C.
P.C.

Kurt Tauer
Kurt Tauer, M.D.

Lee Schwartzberg
Lee Schwartzberg, M.D.

THE WEST CLINIC, P.C.,
A Tennessee Professional Corporation

By: Kurt Tauer
Kurt Tauer, M.D., Secretary

DIRECTORS OF THE WEST CLINIC,

Kurt Tauer
Kurt Tauer, M.D.

Lee Schwartzberg
Lee Schwartzberg, M.D.

Alva B. Weir, III
Alva B. Weir, III, M.D.

Benton Wheeler
Benton Wheeler, III, M.D.

Linda Smiley
Linda Smiley, M.D.

Guy Photopoulos
Guy Photopoulos, M.D.

APPLICATION FOR REGISTRATION

2001 MAR 12 PM 1:09

OF

SECRETARY OF STATE

ASSUMED CORPORATE NAME

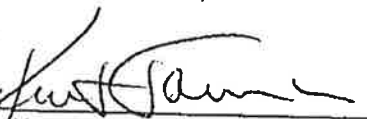
Pursuant to the provisions of Section 48-14-101(d) of the Tennessee Business Corporation Act, the undersigned corporation hereby submits this application:

1. The true name of the corporation is **THE WEST CLINIC, P.C.**
2. The state of incorporation is Tennessee.
3. The corporation intends to transact business in Tennessee under an assumed corporate name.
4. The assumed corporate name the corporation proposes to use is **WEST CANCER CLINIC.**

Dated: February 7, 2001

THE WEST CLINIC, P.C.

By:



Kurt Tauer, M.D., President

Attachment A-6-A
Option to Purchase
Deed

OPTION TO PURCHASE AGREEMENT

THIS OPTION TO PURCHASE AGREEMENT (the “Agreement”) is made and entered into as of August 14, 2018 (the “Effective Date”), between West Clinic, P.C., a Tennessee Professional Corporation (“Buyer”), and Methodist Le Bonheur Healthcare (“Seller”), a Tennessee Professional Corporation, including any affiliates, subsidiaries, or other related business entities to Buyer and Seller.

RECITALS

Seller owns one PET/CT scanner and two linear accelerators located at 7945 Wolf River Road in Shelby County, Tennessee, 38138 (the “Equipment”); and

Seller desires to enter into an option with Buyer whereby Seller grants to Buyer the option to purchase the Equipment, which must be exercised as set forth below.

Therefore, for \$10 cash paid and in consideration of the mutual promises set forth herein and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

SECTION 1 **GRANT OF OPTION**

1.1 Seller grants to Buyer an exclusive option to purchase the Equipment upon the terms and conditions set forth herein (the “Option”).

1.2 The term of Buyer’s Option shall commence on the Effective Date and shall continue for one year from the date of this Agreement (the “Option Period”). This Option Period may be extended at any time prior to its expiration upon the mutual consent of the parties.

1.3 Buyer shall exercise its Option by delivering written notice to Seller within the Option Period by Registered or Certified Mail or in person.

1.4 Notwithstanding the foregoing, this Option shall automatically terminate if Buyer is not successful in obtaining a Certificate of Need for the Equipment from the State of Tennessee Health Services and Development Agency on or before January 1, 2019, provided that the Agency’s decision cannot be overturned on appeal.

SECTION 2
TERMS AND CONDITIONS OF THE PURCHASE

2.1 Upon the exercise of the Option by Buyer as set forth herein, the parties agree to execute a formal purchase agreement, subject to any terms and conditions contained in this Agreement and as mutually agreed upon by the parties. The parties expect that the purchase price shall reflect the fair market value of the Equipment, which shall be approximately \$6,743,706.

SECTION 3
MISCELLANEOUS PROVISIONS

3.1 Any notices required or permitted by this Agreement shall be addressed as follows and delivered to the other party by either registered or certified mail, facsimile, or in person:

If to Seller:

Methodist Health Care Corporation

If to Buyer:

West Clinic, P.C.

[Signature Page Follows on Next Page]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the Effective Date.

SELLER:

Methodist Health Care Corporation

By: _____
Name: _____
Title: _____

BUYER:

West Clinic, P.C.

By: _____
Name: _____
Title: _____

Prepared by and return to:
Jordan Reifler, Esq.
Wyatt, Tarrant & Combs, LLP
1715 Aaron Brenner Drive, Ste. 800
Memphis, Tennessee 38120

Return to:
Stewart G. Austin, Jr.
Glankler Brown, PLLC
6000 Poplar Avenue, Suite 400
Memphis, TN 38119

WARRANTY DEED

THIS INDENTURE, made and entered into this 2nd day of December, 2013, by and between UT MEDICAL GROUP, INC., a Tennessee not-for-profit corporation (herein "Grantor"), and METHODIST HEALTHCARE – MEMPHIS HOSPITALS, a Tennessee not-for-profit corporation (herein "Grantee").

WITNESSETH

That for and in consideration of Ten Dollars (\$10.00), cash in hand paid, and other good and valuable considerations, the receipt of all of which is hereby acknowledged, Grantor has bargained and sold and hereby bargains, sells, conveys and confirms unto Grantee the real estate, situated and being in City of Germantown, County of Shelby, State of Tennessee, more particularly described on Exhibit A attached hereto.

This is the same property conveyed to Grantor by Warranty Deed recorded as Instrument No. GR 4409 in the Register's Office of Shelby County, Tennessee. Tax Parcel No. G02-020-380C.

TO HAVE AND TO HOLD, the aforescribed real estate together with all the appurtenances and hereditaments thereunto belonging or in any wise appertaining unto Grantee, its heirs, successors and assigns in fee simple forever.

Grantor hereby covenants with Grantee that it is lawfully seized in fee of the aforescribed real estate; that it has a good right to sell and convey the same; that the title and quiet possession thereto it will warrant and forever defend against the lawful claims of all persons; and that the same is unencumbered, except for those items set forth on Exhibit B attached hereto.

The words Grantor and Grantee as used herein shall mean "Grantors" and "Grantees", respectively, if more than one person or entity be referred to, and pronouns shall be construed according to their gender and number according to the context hereof.

[SIGNATURE PAGE TO FOLLOW]

[SIGNATURE PAGE TO WARRANTY DEED]

IN WITNESS WHEREOF, Grantor has caused this instrument to be executed by and through its duly authorized officer(s) the day and year first above written.

UT MEDICAL GROUP, INC.

By: Brenda H. Jeter
Brenda H. Jeter, Chief Financial Officer

Date: December 2, 2013

ATTEST: [Signature]

STATE OF TENNESSEE
COUNTY OF SHELBY

Before me, a Notary Public in and for said State and County personally appeared Brenda H. Jeter, with whom I am personally acquainted (or proved on the basis of satisfactory evidence to be the person) and who, upon oath, acknowledged herself to be the Chief Financial Officer of UT Medical Group, Inc., the within named bargainor, a Tennessee not-for-profit corporation, and that she as such officer, executed the foregoing instrument for the purposes therein contained by subscribing the name of the corporation by herself as such officer.

WITNESS my hand and Notarial Seal at office this 2nd day of December, 2013.

My commission expires: _____



Becky M. Epps
Notary Public

I, or we, hereby swear or affirm that, to the best of affiant's knowledge, information and belief, the actual consideration for this transfer or value of the property transferred whichever is greater, is \$22,500,000.00 which amount is equal to or greater than the amount which the property transferred would command at a fair and voluntary sale.

Brenda H. Jeter
Affiant

Subscribed and sworn to before me this 2nd day of December, 2013.

Becky M. Epps
Notary Public

My commission expires:



Property Address:

7945 Wolf River Boulevard
Germantown, Tennessee 38138

Mail tax bills to:

~~Comptroller~~

Mail tax bill owner
UT Medical Group, Inc. Methodist Healthcare Memphis Hospitals
1407 Union Ave., Suite 700
Memphis, TN 38104-3641

State Tax	\$83,250.00
Register's Fee	3.00
Recording Fee	25.00
Total	\$83,278.00

EXHIBIT A

PROPERTY DESCRIPTION

Parcel I:

Lot 7, Phase 1, First Addition, Wolf River Center as recorded in Plat Book 149 Page 34 and being the UT Medical Group, Inc. property as described in Instrument GR 4409 in Germantown, Shelby County, Tennessee:

Beginning at a point on curve at the intersection of the northeast line of Brierbrook Road (54 foot right-of-way) with the east line of Lot 5A, Re-Subdivision of Lot 5, Wolf River Center as recorded in Plat Book 197 Page 71, said point being 975.6 feet east of the east line of South Germantown Road as measured along the north line of Brierbrook Road (found chisel mark 0.9 foot south); thence North 13 degrees 40 minutes 03 seconds East with east line of said subdivision a distance of 888.71 feet to a pk nail found on a curve in the south line of Wolf River Boulevard (106 foot right-of-way); thence southeasterly along a curve to the right having a radius of 1347.00 feet with the south line of Wolf River Boulevard a distance of 513.21 feet (chord = South 53 degrees 20 minutes 10 seconds East 510.11 feet, delta = 21 degrees 49 minutes 47 seconds) to a point in the west line of Lot 3, Phase II, Wolf River Center as recorded in Plat Book 146 Page 89 (found chisel mark 0.5 feet east); thence South 03 degrees 03 minutes 37 seconds West with the west line of said Lot 3 a distance of 526.98 feet to an iron pin in a northwest line of said Lot 3; thence South 69 degrees 09 minutes 52 seconds West with the northwest line of said Lot 3 a distance of 538.97 feet to an iron pin set on a curve in the northeast line of Brierbrook Road; thence northwestwardly along a curve to the left having a radius of 447.00 feet with the northeast line of Brierbrook Road a distance of 182.66 feet (chord = North 28 degrees 46 minutes 37 seconds West 181.39 feet, delta = 23 degrees 24 minutes 45 seconds) to the point of beginning and containing 9.63 acres.

Parcel II:

An easement for ingress and egress on and over a portion of Lot 5, Phase I, First Addition Wolf River Center, as recorded in Plat Book 149, Page 34 in the Shelby County Register's Office, said easement being contained in Reciprocal Driveway Easement Agreement of record at Instrument No. JE 6008, re-recorded at Instrument No. JF 7060 of the records of the Register's Office and the entire easement being more particularly described as follows:

Beginning at a point in the south line of Wolf River Boulevard (106 foot R/W), said point being 956.63 feet east of the tangent intersection with the east line of Germantown Road (56.0 feet center to east line), as measured along said south line; Thence South 13°40'03" West 365.00 feet to a point; Thence North 76°19'57" West 22.50 feet to a point; Thence North 13°40'03" East 349.24 feet to a point; Thence North 31°19'57" West 35.46 feet to a point in the south line of Wolf River Boulevard, Thence along said south line and along a curve to the right having a radius of 1,347.00 feet an arc distance of 48.48 feet (chord = South 65°15'41" East - 48.48 feet) to the point of beginning.

EXHIBIT B
EXCEPTIONS

Matters as shown on survey by Harris & Associates Land Surveyors, LLC dated November 4, 2013.

2013 City of Germantown and 2013 Shelby County Real Property taxes due but not yet delinquent, and all subsequent years, not yet due and payable, as to the Easement Parcel.

2014 City of Germantown and 2014 Shelby County Real Property taxes and all subsequent years, not yet due and payable, as to the Fee Parcel.

Any taxes or assessments not posted on the records of the taxing authority(ies) of which land described in Schedule A hereof is subject, including but not limited to: Supplemental, Revised, and/or Corrected Assessments pursuant to T.C.A. Section 6-5-603 et seq. or Back Assessments pursuant to T.C.A. Section 67-1-1001 et seq.; or taxes based on a change in the classification of the insured Land (Roll Back Taxes) pursuant to T.C.A. Section 67-5-1001 et seq.

Subdivision Restrictions, Building Lines and Easements of record in Plat Book 139, Page 10; Plat Book 140, Page 45; Plat Book 145, Page 80; Plat Book 147, Page 51; and Plat Book 149, Page 34, all in the Register's Office of Shelby County, Tennessee.

Perpetual Greenway Easement of record at Instrument No. CN 7740 in the said Register's Office.

Reciprocal Driveway Easement Agreement of record at Instrument No. JE 6008, and re-recorded at Instrument No. JF 7060, in the said Register's Office.

Memphis Light, Gas & Water Easement of record at Instrument No. DJ 8400 in the said Register's Office.



Tom Leatherwood
Shelby County Register

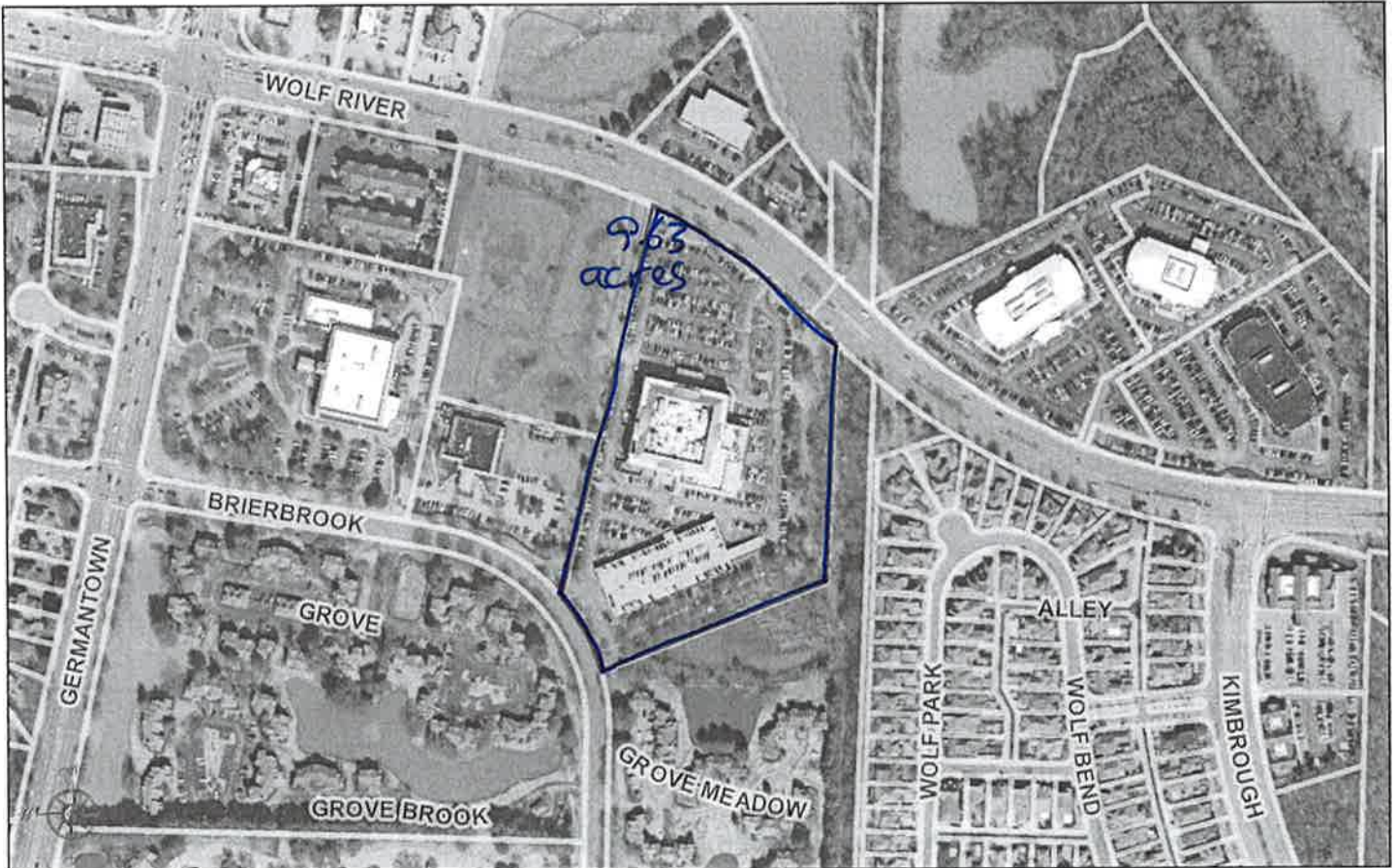
As evidenced by the instrument number shown below, this document
has been recorded as a permanent record in the archives of the
Office of the Shelby County Register.

13143313	
12/03/2013 - 11:00 AM	
5 PGS	
BUDDY	1361267-13143313
VALUE	22500000.00
MORTGAGE TAX	0.00
TRANSFER TAX	83250.00
RECORDING FEE	25.00
DP FEE	2.00
REGISTER'S FEE	1.00
WALK THRU FEE	5.00
TOTAL AMOUNT	83283.00
TOM LEATHERWOOD	
REGISTER OF DEEDS SHELBY COUNTY TENNESSEE	

Attachment 6-B-1

Plot Plan

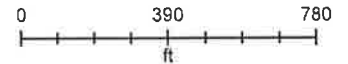
7945 Wolf River



**TOM LEATHERWOOD, REGISTER OF DEEDS
SHELBY COUNTY, TENNESSEE**

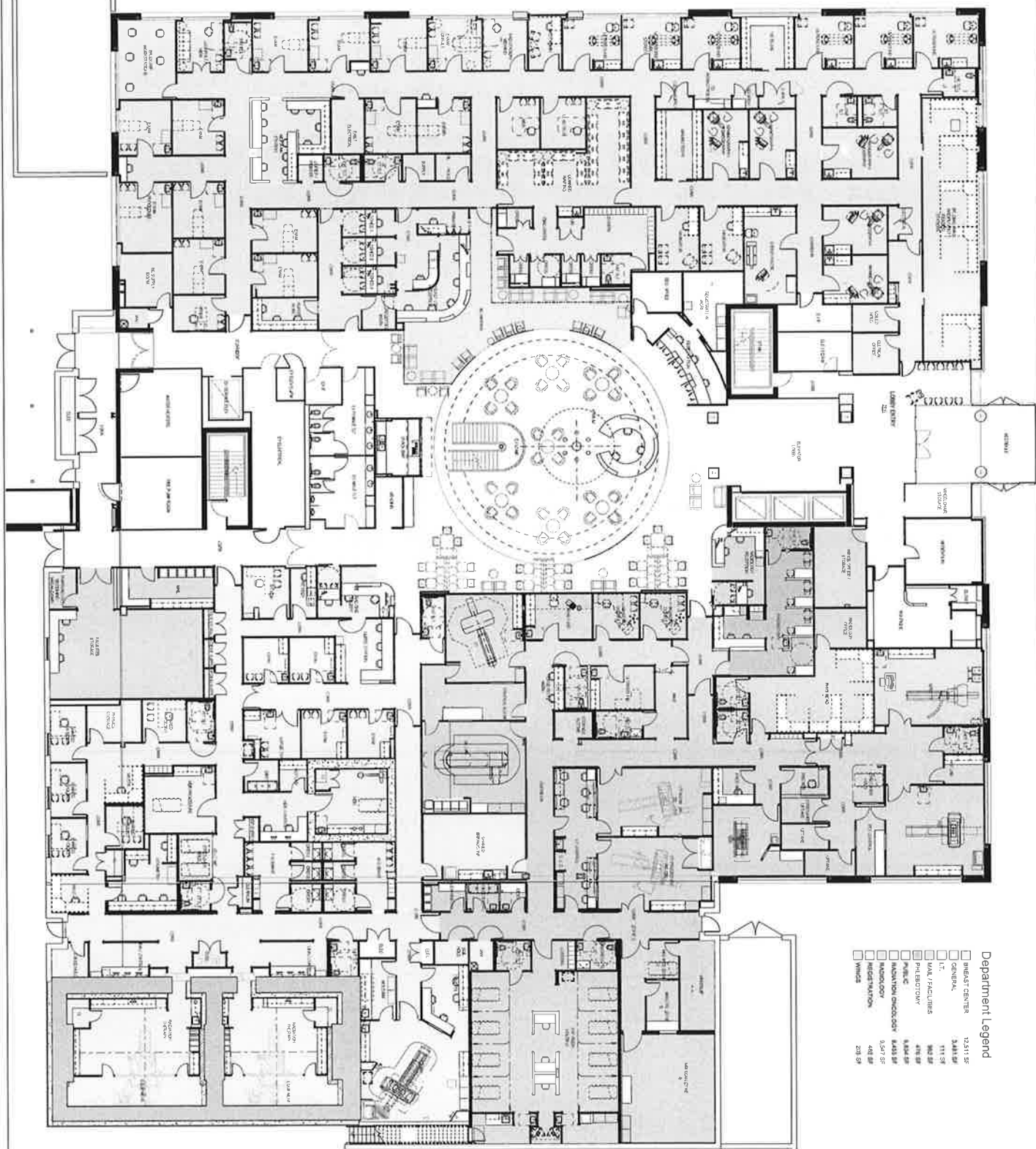
DISCLAIMER: PROPERTY TAX MAPS AND PARCEL BOUNDARIES DO NOT REFLECT ACCURATE SURVEY INFORMATION OR EXACT LEGAL OWNERSHIP BOUNDARIES AND ARE ONLY PROVIDED FOR GENERAL INFORMATION PURPOSES. THEREFORE, THEY SHOULD NOT BE RELIED UPON AS A REPRESENTATION OF ANY PROPERTY FOR ANY PURPOSE

MAP DATE August 13, 2018



Attachment 6-B-2

Floor Plan



Department Legend

<input type="checkbox"/> BREAST CENTER	12.511 S
<input type="checkbox"/> GENERAL	3.4481 S
<input type="checkbox"/> I.T.	111 S
<input type="checkbox"/> MAIL/FACILITIES	360 S
<input type="checkbox"/> PHLEBOTOMY	416 S
<input type="checkbox"/> PHYSIC	8.534 S
<input type="checkbox"/> RADIATION ONCOLOGY	8.453 S
<input type="checkbox"/> RADIOLOGY	9.547 S
<input type="checkbox"/> REGISTRATION	448 S
<input type="checkbox"/> WHICIS	208 S

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A diagram showing a cross-section of a cell wall with four labeled regions: A (top), B (middle), C (bottom), and D (side).

**WEST CANCER CENTER
PACKAGE B -
RENOVATIONS &
ADDITION**

Project No. _____
Cost Period _____
Contract No. _____
Company # 505 _____

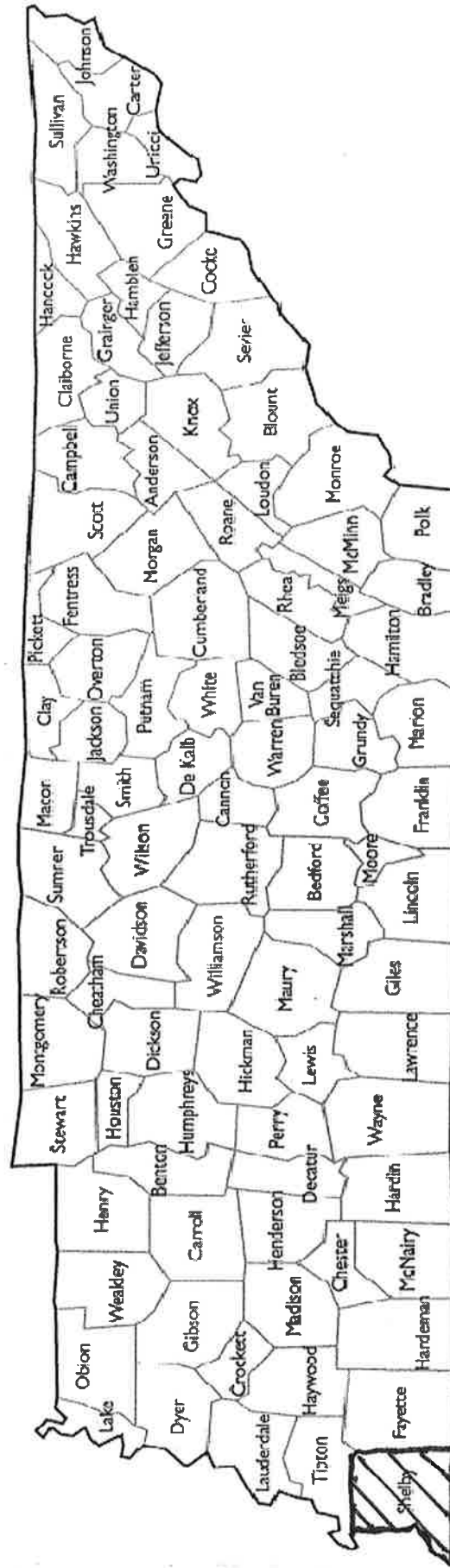
DATE: 09/01/13
**LEVEL 1
DEPARTMENT FLOOR
PLAN**

DEPARTMENT FLOOR PLAN
L1

Attachment B, Need 3-3

Map of Service Area by County

County Level Map



Service Area

Attachment B, Economic Feasibility - 2

Bank Letter

**Attachment C, Contribution to the Orderly Development
Of Health Care**

Proof of Publication

**The Commercial Appeal
Affidavit of Publication**

**STATE OF TENNESSEE
COUNTY OF SHELBY**

Personally appeared before me, Glenn W. Edwards, a Notary Public, Helen Curl, of MEMPHIS PUBLISHING COMPANY, a corporation, publishers of The Commercial Appeal, morning and Sunday paper, published in Memphis, Tennessee, who makes oath in due form of law, that she is Legal Clerk of the said Memphis Publishing Company, and that the accompanying and hereto attached advertisement was published in the following editions of The Commercial Appeal, to-wit:

August 10, 2018

Helen Curl

Subscribed and sworn to before me this 10th day of August, 2018.

Glenn W. Edwards
STATE OF TENNESSEE
NOTARY PUBLIC
Notary Public

My commission expires January 20, 2020.

WALLER LANSDEN DORTCH & DAVIS LLP

NASHVILLE CITY CENTER
511 UNION STREET, SUITE 2700
POST OFFICE BOX 198966
NASHVILLE, TENNESSEE 37219-8966

Regions Bank General

87-1
640

Date:

August 15, 2018

243147

Pay: Sixty-eight thousand seven hundred three and 02/100***** \$ ***68,703.02***

PAY
TO THE
ORDER OF:

Health Services and Development Agency
Andrew Jackson Bldg, 9th floor
502 Deaderick Street
Nashville, TN 37243

Memo:

⑈ 243147 ⑈ ⑆064000017⑆ 0001920307⑈

Payee: Health Services and Development Agency
Vendor ID: HSDA

Check #: 243147
Check Date: August 15, 2018

<u>Inv #</u>	<u>Inv Date</u>	<u>G/L Acct</u>	<u>Client</u>	<u>Matter</u>	<u>Narrative</u>	<u>Amount</u>	<u>Inv Total</u>
8-15-18-KHL-LG	08/15/2018		029582	85724	VENDOR: TN Health Services and Development Agenc INVOICE#: 8-15-18-KHL-LG DATE: 8/15/2018 West Cancer Center-Germantown: CON Filing Fee	\$68,703.02	\$68,703.02
Invoice Totals:						\$68,703.02	\$68,703.02

Laurie
-21

Legal Notices

ties' right to redeem the property as required by 26 U.S.C. 7425 and T.C.A. §67-1-1433. This property is being sold with the express reservation that the sale is subject to confirmation by the lender or trustee. If the sale is set aside for any reason, the Purchaser at the sale shall be entitled only to a return of the purchase price. The Purchaser shall have no further recourse against the Mortgagor, the Mortgagee or the Mortgagee's attorney.

MWZM File No. 18-000670-670-1 Mackie Wolf Zientz & Mann, P.C., Substitute Trustee(s)

ADJOURN THE DAY OF THE SALE TO ANOTHER DAY, TIME AND PLACE CERTAIN WITHOUT FURTHER PUBLICATION, UPON ANNOUNCEMENT AT THE TIME AND PLACE FOR THE SALE SET FORTH ABOVE. THE TERMS OF SALE ARE CASH, ANY TAXES OR FEES WILL BE THE RESPONSIBILITY OF THE PURCHASER. IF THE SALE IS SET ASIDE FOR ANY REASON, THE PURCHASER AT THE SALE SHALL BE ENTITLED ONLY TO A RETURN OF THE PURCHASE PRICE. THE PURCHASER SHALL HAVE NO FURTHER RECOURSE AGAINST THE GRANTOR, THE GRANTEE, OR THE TRUSTEE.

OTHER INTERESTED PARTIES: ESTATE OF VIRGINIA CRAWFORD AND TAMINKA CRAWFORD AND TENNESSEE HOUSING DEVELOPMENT AGENCY AND TAYLISA CRAWFORD AND SHEENA WITHERSPOON AND SHEEREE CRAWFORD. THIS IS AN ATTEMPT TO COLLECT A DEBT AND ANY INFORMATION OBTAINED WILL BE USED FOR THAT PURPOSE. If applicable, the notice requirements of T.C.A. 35-5-101 have been met. All right of equity of redemp-

Legal Notices

tion, statutory and otherwise, and homestead are expressly waived in said Deed of Trust, but the undersigned will sell and convey only as Substitute Trustee.

If the U.S. Department of Treasury/IRS, the State of Tennessee Department of Revenue, or the State of Tennessee Department of Labor or Workforce Development are listed as Interested Parties in the advertisement, then the Notice of this foreclosure is being given to them and the Sale will be subject to the applicable governmental entity's approval.

RESTRICTIONS: Subject to restrictions for Cottonwood Acres Subdivision as set out in Book 297, page 118 and as shown on plat recorded in Plat Cabinet 1, slide 15 of the Register's Office of Lauderdale County, Tennessee.

Being designated as Map 94L, Group C, Parcel 24 in accordance with the Tax Assessor's Office of Lauderdale County, Tennessee.

Being the same property conveyed to Andra Carter by deed recorded in Book 547, page 838 of the Register's Office of Lauderdale County, Tennessee.

Street Address: 302 Robin Dr, Ripley, Tennessee 38063
Secondary Property Address: Ripley
Parcel Number: 94L-C-024.00
Current Owner(s) of Property: Andra Carter

The street address of the above described property is believed to be 302 Robin Dr, Ripley, Tennessee 38063, but such address is not part of the legal description of the property sold herein and in the event of any discrepancy, the legal description herein shall

Legal Notices

control. This sale is subject to, without limitation, all matters shown on any applicable recorded plat; any unpaid taxes; any restrictive covenants, easements, or setback lines that may be applicable; any statutory right of redemption of any governmental agency, state or federal; any prior liens or encumbrances including those created by a fixture filing or any applicable homeowners' association dues or assessments; all claims or other matters, whether of record or not, which may encumber the property. The purchaser price, the Substitute Trustee may deem the sale final in which case the purchaser shall have no remedy. The real property will be sold AS IS, WHERE IS, with no warranties or representations of any kind, express or implied, including without limitation, warranties regarding condition of the property or marketability of title.

This office may be a debt collector. This may be an attempt to collect a debt and any information obtained may be used for that purpose. Shapiro & Ingle, LLP Substitute Trustee, 10130 Perimeter Parkway, Suite 400, Charlotte, NC 28216 Phone: (704) 333-8107 Fax: (704) 333-8156 www.shapiro-ingle.com File No. 18-116016

Garage Sale
1130 HAYNE RD - Friday August 10th, 7:00 am to 1pm. 1130 Hayne Rd, Yorkshire Forest Area. Great household furnishings, furniture, lots of great misc. books or old jewelry. Will be held in the carport towards the back of the house

OLIVE BRANCH MOVING SALE
Everything Must Go. Don't miss this sale. All items reasonably priced & nice. Aug 10 & 11. Fri & Sat. 8 a.m. - 4 p.m. 6031 Choctaw Trails

Estate Sales
BARTLETT ESTATE SALE
5785 Magnolia Woods Lane
9 a.m. - 4 p.m. daily
Fri. Sat. Sun. Aug. 10, 11, & 12
House full: Beautiful furniture, beds, tables, curio & china cabinets, sofa, kitchen packed dishes, china, pots, pans, glassware, coke collection, tea cart, sewing machine, quilts, art, TV, videos, albums, Star Wars & Star Trek collectibles, miniatures, clothes, books, linens, lots of tools, yard equipment, mower, ladders, garden swing, too much to list.

Critchfield Estate Sales
Pics: estatesales.net
901.301.0666

CHARLOTTE'S ESTATE SALES
LIFETIME PICKERS
ESTATE SALE
196 Lenzi Rd. Byhalia, MS
Fri. Aug 10, 9-3. Sat. Aug 11, 9-4. Sun. Aug 12, 10-4
Amazing sale! 100's of primitive & collectibles, antique tools, old signs, beer signs, antique metal pedal cars, toys & more. Vintage coke & pepsi machines, antique farming tools, massive cookie jar collection. Huge building full - more than you could possibly imagine!
Rain or Shine! Pics: estatesales.net 901-692-7493

DEB WADE ESTATE SALES
9679 Joe Lyon Blvd.
Olive Branch, MS 38654
Fri. 9-4. Sat. 9-4. Sun. 9-3
See pics & directions at www.estatesales.net 901-486-2842

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Laundry Onsite.
EARN FREE RENT.
CALL NOW: 901-250-1480

BARTLETT
Pet Friendly Studio Apartments!
No Credit Check!
All units fully furnished.
Utilities & Cable INCLUDED.
EARN FREE RENT.
CALL NOW: 901-250-1480

MEMPHIS - MOVE IN TODAY!
No long-term lease and Bad Credit OK. FULL Kitchenettes. FREE Utilities, cable and WIFI. Laundry onsite.
PET FRIENDLY. Low weekly & monthly payment options. Earn FREE STAYS, ask us how! Call- 901-472-8280.

MIDTOWN - Studios & 1 BRs
Quiet. Util inc. \$600 & up. No smoke/no pets. 901-276-7472

Apartment - Unfurn.
3 BR / 2 BA \$605
VALLEY FORGE APARTMENTS
EHO 345-6867
MRGAPARTMENTS.COM

APPLETREE APTS.
2 BR ONLY \$469 / MO.
(901) 552-5669 EHO
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APTS IN 55 LOCATIONS
www.mrgapartments.com
Makowsky Ringel
Greenberg, LLC
(901)683-2220

Homes Unfurnished
Affordable Rental Homes
2 & 3 BR. \$450 mo.-up, \$300 dep. Free Application. 901-212-7431

COLLIERVILLE 104 Wilson 3br
1 ba, 1000 sf. All new appls. & new cent. AC/heating. Lawn service included. \$1250 mo. \$1250 dep. 901-603-0978

EAST MEMPHIS
Single Family Home for Rent
3481 Walnut Grove Rd.
Newly Remodeled, 3 Bedrooms, 2 Baths, Eat in Kitchen, Dining Room, Living Room and Den. Lawn service included. \$1400 a month with \$500 deposit. 901-452-0040 Sharon

JACKSON AVE. NATIONAL
DUPLEX 1 br, 1 ba, \$450 mo. \$300 dp. Free appl. 901-212-7431

NORTH 829 Alaska, 4BR., 1BA., W/D, CA, \$600 mo.-dp.
901-606-2561

ORANGE MOUND 2 br,
1 ba, \$450 mo. \$300 dep. Free appl. 901-212-7431

PENDLETON/SEMMES
2754 Lola, 3BR, 1Ba, Lr. Dr. ch/a, w/d, cpt. \$600+dp 901-606-2561

Homes Unfurnished

SOUTH MEMPHIS 2 br, central h/a, hwd floors, appliances. \$525 mo. \$300 dep. 481-1929

Rooms Furn/Unfurn

AIRPORT AREA - Riverside Dr., Highland Heights, Poplar and Scott, \$85-\$125.
(901)359-4639

AIRWAYS/PARK Newly decorated furn. BR, w/d, h/a, phone. Mitchell Forestry & Wildlife Services - Broker
Go to: mitchellforestry.com or 662-284-8104

Cemetery Lots

MEMORIAL GARDENS - Germantown (4 plots). Best Offer (931) 644-9184

MEMORIAL PARK - POPLAR
(1) plot. Crestlawn South lot 6 \$2500. Call for more information (662)996-7117

MEMORIAL PARK 1-PLOT in the Rose Hill Section. \$3200. Sells for \$6700. Will pay transfer fee. (901)581-9048

MEMORIAL PARK
3 Cemetery Lots.
West Lawn 125, # 2, 3 & 4. \$10,000. (662)838-3922

MEMORIAL PARK Cemetery
Garden of Serenity
2 mausoleums \$5000 each. (901)283-0018

MEMPHIS MEMORY GARDENS
3 adj lots in the Garden of the Last Supper. Close to the road \$2500 each neg Buyer pays the transfer fee. 256-335-1831 (256)335-1831

Property Management

PROPERTY MANAGEMENT
Brookfield Properties is a 25-year-old real estate company that is currently 98% leased up. We would like to manage your properties.
Call Jeff Boone (901)685-5585

Recreation

Camper & RV's

2005 FLEETWOOD JAMBOREE
- 2005 Fleetwood Jamboree, 31k miles, sleep 6, \$7000 sale price. Contact: clarisburcin1@gmail.com (615)398-4071.

Transportation

Automobiles for Sale

AUDI Q3 - 2018. White, like new, \$30,921 incl. \$599 doc, excl. tit. #27180. Ask for Keino Spring, 901-301-4912

BUD DAVIS CADILLAC

CADILLAC ATS - 2013. Silver coast. Very, very low miles. Ask for Keith Dial, 901-218-9105, Special Price!

BUD DAVIS CADILLAC

CADILLAC ATS SEDAN - 2015. Great miles, stylish look. Stk# 27163. Jerry Five Ash, 901-497-0575

BUD DAVIS CADILLAC

CADILLAC CTS - 2010. Tan, looks newer, what a pretty car with low miles, mature owner. Call David Poley, 901-238-8872

BUD DAVIS CADILLAC

CADILLAC CTS - 2014. Very well taken care of. Sale \$25,931 incl \$599 doc fee, excl tit. Stk #27172A. See Barbara Wright, 901-761-1900

BUD DAVIS CADILLAC

CADILLAC XTS - 2015. Big luxury! White. Loaded! \$30,988 incl \$599 doc, excl tit. Stk #27181. Ask for Alex, 901-288-7600

BUD DAVIS CADILLAC

LEXUS ES 300 - 2007. Silver New Michelin tires, 1 owner, \$7200 firm. (901)848-2831.

Automobiles for Sale

CADILLAC XTS - 2018. luxury car, certified, better than that! Ca Wright, 901-761-1900
BUD DAVIS CAD

MERCEDES-I
Low price High qty;
2 Indoor Showrooms
150+ Mercedes in stock
w/100k extd warranty
15,000+ Happy Clients
All trades welcome
Excellent financing!
w/approved credit
Sales • Service • Body

SEEKING TITLE:
2006 INFINITI I
VIN: JNKVC51E46M
Anyone with interest vehicle, contact for 10-bus. days by cert return/receipt. requ Turner, 248 Williford phis, TN. 38112

NOTICE OF SUNSET PUBLIC HEARING

In accordance with Title 4, Chapter 29, Tennessee Code Annotated, the Government Operations Committees of the Tennessee General Assembly will conduct a public hearing to receive testimony on whether the entities listed below should be continued, restructured, or terminated. The hearings will be held in the Legislative Plaza, Nashville, Tennessee, as indicated below. Pertinent public testimony is invited.

Wednesday, August 22, 2018 at 9:00 a.m.
Senate Hearing Room I, Cordell Hull Building

Board of Appeals, Department of Human Resources
Board of Claims
Board of Trustees of the College Savings Trust Fund Program
Department of Human Resources
Employee Suggestion Award Board
Information Systems Council
Tennessee Claims Commission
Tennessee Consolidated Retirement System
Trial Court Vacancy Commission
Underground Utility Damage Enforcement Board

Any changes in the above schedule which may become necessary will be announced at the Government Operations Committees' website at www.capitol.tn.gov/jointcommittees/gov-apps/. For additional information or to request special accommodations for individuals with disabilities, contact: Kandi Thomas, Assistant Director, Division of State Audit, Nashville, Tennessee; telephone: (615) 747-5274; e-mail: Kandi.Thomas@cot.tn.gov. Request for special accommodations should be made at least 24 hours prior to the meeting whenever possible.

MC-087174

Legal Notices

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that:

West Cancer Center, owned by: West Clinic, PC with an ownership type of professional corporation, and to be managed by itself, intends to file an application for a Certificate of Need for the initiation of linear accelerator services and PET/CT services located at 7945 Wolf River Blvd., Germantown (Shelby County), Tennessee 38138. The applicant will initiate these services with existing major medical equipment, including 2 linear accelerators and 1 PET/CT scanner, that are already utilized by the West Clinic for its patients. The equipment is currently owned by Methodist, but will be transferred to West Clinic with the approval of this application. The anticipated project costs are approximately \$8,300,000.00.

The anticipated date of filing the application is August 15, 2018.

The contact person for this project is Kim Harvey Looney, Esq., Attorney, who may be reached at Waller Landon Dorch & Davis LLP, 511 Union Street, Suite 2700, Nashville, Tennessee 37219, (615) 850-8722.

Upon written request by interested parties, a local Face-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1407(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

MC-087170

Fin
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State of Tennessee

Health Services and Development Agency

Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243

www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

September 1, 2018

Ms. Kim Harvey Looney, Esq.
Waller Lansden Dortch & Davis LLP
511 Union Street, Suite 2700
Nashville, TN 37219

RE: Certificate of Need Application – West Cancer Center - CN1807-038
The initiation of linear accelerator and PET/CT services at 7945 Wolf River Boulevard, Germantown (Shelby County), TN 38138. The West Cancer Center is currently a collaboration between Methodist Le Bonheur Healthcare (Methodist), the University of Tennessee Health Science Center (UT), and the West Clinic. The medical equipment subject to this application are two linear accelerators and one PET/CT scanner that are presently used for cancer diagnosis and treatment for West Cancer Center patients. The business relationship between the three parties will end effective January 1, 2019. The applicant plans to purchase the existing site and medical equipment from Methodist Le Bonheur Healthcare, thereby becoming the sole owner, and continuing its use as part of the West Cancer Center. If approved, the medical equipment owned by Methodist will be transferred to the West Clinic. The applicant is owned by West Clinic, P.C. The estimated project cost is \$12,017,055.02.

Dear Ms. Looney:

This is to acknowledge the receipt of supplemental information to your application for a Certificate of Need. Please be advised that your application is now considered to be complete by this office.

Your application is being forwarded to Trent Sansing at the Tennessee Department of Health, Division of Policy, Planning, and Assessment for Certificate of Need review. You may be contacted by Mr. Sansing or someone from his office for additional clarification while the application is under review by the Department. Mr. Sansing's contact information is Trent.Sansing@tn.gov or 615-253-4702.

In accordance with Tennessee Code Annotated, §68-11-1607, et seq., as amended by Public Chapter 780, the 30-day review cycle for **CONSENT CALENDAR** for this project began on September 1, 2018. The first 30 days of the cycle are assigned to the Department of Health, during which time a public hearing may be held on your application. You will be contacted by a representative from this Agency to establish the date, time and place of the hearing should one be requested. At the end of the 30-day period, a written report from the Department of Health or its representative will be forwarded to this office for Agency review. You will receive a copy of their findings. The Health Services and Development Agency will review your application on October 24, 2018.

Ms. Looney
Page 2

Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. § 68-11-1607(d):

- (3) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive Director and a written summary of such communication shall be made part of the certificate of need file.
- (4) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is deemed complete and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the certificate of need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Should you have questions or require additional information, please contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "Melanie M. Hill" followed by a stylized monogram or initials.

Melanie M. Hill
Executive Director

cc: Trent Sansing, TDH/Health Statistics, PPA



State of Tennessee

Health Services and Development Agency

Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243

www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

MEMORANDUM

TO: Trent Sansing, CON Director
Office of Policy, Planning and Assessment
Division of Health Statistics
Andrew Johnson Tower, 2nd Floor
710 James Robertson Parkway
Nashville, Tennessee 37243

FROM: Melanie M. Hill *MMH/MF*
Executive Director

DATE: September 1, 2018

RE: Certificate of Need Application
West Cancer Center- CN1807-038
CONSENT CALENDAR

Please find enclosed an application for a Certificate of Need for the above-referenced project.

This application has undergone initial review by this office and has been deemed complete. It is being forwarded to your agency for a **CONSENT CALENDAR** thirty (30) day review period to begin on September 1, 2018 and end on October 1, 2018.

Should there be any questions regarding this application or the review cycle, please contact this office.

Enclosure

cc: Ms. Kim Harvey Looney, Esq.



State of Tennessee
Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

2018 AUG 15 PM 3:00

LETTER OF INTENT

The Publication of Intent is to be published in the Commercial Appeal which is a newspaper
(Name of Newspaper)
of general circulation in Shelby, Tennessee, on or before August 10, 20 18
(County) (Month/Day) (Year)
for one day.

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 *et seq.*, and the Rules of the Health Services and Development Agency, that:

West Cancer Center
(Name of Applicant)

(Facility Type-Existing)

owned by: West Clinic, PC with an ownership type of professional corporation

and to be managed by: itself intends to file an application for a Certificate of Need

for [PROJECT DESCRIPTION BEGINS HERE]: the initiation of linear accelerator services and PET/CT services located at 7945 Wolf River Blvd., Germantown (Shelby County), Tennessee 38138. The applicant will initiate these services with existing major medical equipment, including 2 linear accelerators and 1 PET/CT scanner, that are already utilized by the West Clinic for its patients. The equipment is currently owned by Methodist, but will be transferred to West Clinic with the approval of this application. The anticipated project costs are approximately \$8,300,000.00.

The anticipated date of filing the application is: August 15, 20 18

The contact person for this project is Kim Harvey Looney, Esq. Attorney
(Contact Name) (Title)

who may be reached at: Waller Lansden Dortch & Davis LLP 511 Union Street, Suite 2700
(Company Name) (Address)

Nashville TN 37219 615 / 850-8722
(City) (State) (Zip Code) (Area Code) (Phone Number)

Kim H. Looney
(Signature)

August 10, 2018
(Date)

Kim.Looney@wallerlaw.com
(Email-Address)

The Letter of Intent must be filed in triplicate and received between the first and the tenth day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

Supplemental #1 (Original)

West Cancer Center
-Germantown

CN1808-038



Waller Lansden Dortch & Davis, LLP
511 Union Street, Suite 2700
P.O. Box 198966
Nashville, TN 37219-8966

Supplemental #1

August 29, 2018

615.244.6804 fax
615.244.6804
wallerlaw.com
9:33 A.M.

Kim Harvey Looney
615.850.8722 direct
kim.looney@wallerlaw.com

August 29, 2018

VIA HAND DELIVERY

Phillip Earhart
HSD Examiner
State of Tennessee
Health Services and Development Agency
Andrew Jackson Building
9th Floor
502 Deaderick
Nashville, TN 37243

Re: West Cancer Center - Germantown - CN1808-038

Dear Phillip:

This letter is submitted as the supplemental response to your letter dated June 22, 2018, wherein additional information or clarification was requested regarding the above-referenced CON application.

1. Section A, Project Details, Item 4.B

Describe the existing or proposed ownership structure of the applicant, including an ownership structure organizational chart. Explain the corporate structure and the manner in which all entities of the ownership structure relate to the applicant. As applicable, identify the members of the ownership entity and each member's percentage of ownership, for those members with 5% ownership (direct or indirect) interest.

Response: West Cancer Center is a dba for the West Clinic, P.C. There are 20 physician shareholders in the West Clinic, P.C. Each owns 5% of the physician practice. Please see a list of the physician shareholders and an organizational chart included as Attachment A, Project Details, Item 4.B.

2. Section A, Project Details, Item 6.A

The option to purchase agreement for medical equipment if noted. However, please provide a fully executed option to purchase agreement for the acquisition of the one PET/CT scanner and two linear accelerators.

Response: Please see executed option to purchase agreement for the linear accelerators and the PET/CT included as Attachment A, Project Details, Item 6.A.

Please provide a fully executed document including Option to Purchase Agreement for the acquisition of the project site that includes the anticipated purchase price and will be valid on the date of the Agency's consideration of the certificate of need application.

Response: Please see executed Option to Purchase Agreement for the project site included as Attachment A, Project Details, Item 6A. While the applicant will purchase the entire site, only the portion allocated to the PET/CT and linear accelerators and any proportion of ancillary/common spaces are included as a part of this project.

3. Section A, Project Details, Item 6.B (2) and 6.B (3)

The floor plan is noted. However, please provide a revised floor plan that notes the location of the PET/CT and linear accelerators.

Response: Please see copy of floor plan with the location of the PET/CT and the linear accelerators included as Attachment A, Project Details, Item 6.B(2).

It is noted there is a bus service that stops a couple of blocks from the practice site. Please clarify if there are sidewalks for pedestrians for the remainder of two blocks.

Response: There are sidewalks with the exception of the construction site next door, which is where Campbell Clinic is relocating. The applicant anticipates that when that construction is complete, the sidewalk will be extended so it will be complete also.

4. Section A, Project Details, Item 13 (B)

The option to purchase agreement for medical equipment for the fair market price of \$6,743,706 is noted. However, please itemize the purchase between the two linear accelerators and one PET/CT.

Response: The breakdown of the \$6,743,706 is as follows:

- PET/CT Wolf River - \$1,412,602
- Lin Acc #1 Infinity - \$2,367,971
- Lin Acc #2 VersaHD - \$2,963,133

As stated in the application, an appraisal is in the process of being performed to determine FMV. The dollar figures above represent the initial purchase price of the equipment when new, which is expected to be greater than FMV.

5. Section A, Project Details, Item 13 (F)

It appears the two linear accelerators subject to this application is less than 5 years old. If the equipment has been approved by the FDA within the last five years, please provide FDA approval documentation.

Response: The two linear accelerators are less than 5 years old, and have been in service for approximately 3 years. Please see attached FDA documentation included as Attachment A, Project Details, Item 13(F).

6. Section B. Need Item 1. (Project Specific Criteria – MRT Service)

Item 6.B-Please provide documentation that the proposed MRT units are housed in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

Response: Please see documentation included as Attachment B, Need Item 1 (Project Specific Criteria - MRT Service).

Item 6.E.- It is noted the applicant will receive accreditation from APEX. What is APEX and how does it relate to this project?

Response: APEX is a practice accreditation program from the world's premier radiation oncology society. The American Society for Radiation Oncology (ASTRO) created this unique program to support quality improvement in radiation therapy practices. Facilities that obtain practice accreditation demonstrate the systems, personnel, policies and procedures needed to meet APEX standards for high quality patient care. It is another accreditation program to which the applicant has applied.

7. Section B. Need Item 1. (Project Specific Criteria – PET Service)

Item 6.a.- If the proposed PET unit has been approved by the FDA within the last five years please provide documentation that verifies the proposed PET unit is certified by the United States Food and Drug Administration (FDA).

Response: The PET/CT was approved more than 5 years ago.

Item 6.b.-Please provide documentation that the proposed PET procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specification, and licensing agencies' requirements.

Response: Please see documentation included as Attachment B, Need Item 1-6.b (Project Specific Criteria - PET Service).

Item 6.d. – Please provide documentation for the following:

- Documentation from the current PET equipment owner that current protocols that assures that all clinical PET procedures performed are medically necessary and will not unnecessarily duplicate other services will be transferred to the applicant.

Response: Please see policies for the West Cancer Center included as Attachment B, Need Item 1-6.d (Project Specific Criteria - PET Service). The applicant will continue to adhere to these policies after the ownership is changed.

- Clinical supervision and interpretation services will be provided by physicians who are licensed to practice medicine in the state of Tennessee and are board certified in Nuclear Medicine or Diagnostic Radiology.

Response: West Clinic has three employed radiologists who perform these clinical supervision and interpretation services. The three physicians are Dr. Daniel Knight Powell, Dr. Scott Leslie Baum and Dr. William Alexander Lankford. A copy of the certification paperwork for each from the American Board of Radiology and their CVs is included as Attachment B, Need, Item 1-6.d (Project Specific Criteria-PET Service).

- Physicians that will provide interpretation serves has documented experience and training, credentialing, and/or board certification in the appropriate specialty and in the use and interpretation of PET procedures.

Response: Please see response above and Attachment B, Need, Item 1-6.d (Project Specific Criteria-PET Service), for information on Drs. Lankford, Baum and Powell.

Item 8.b.-Please provide documentation that the service area population experiences a prevalence, incidence and/or mortality from cancer, heart disease, neurological impairment or other clinical conditions applicable to PET unit services that is substantial higher than the State of Tennessee average.

Response: The PET/CT services provided by the applicant are for cancer conditions only. Please see table included as Attachment B, Need, Item 1-8.b (Project Specific Criteria-PET Service), for data on several cancer conditions by site in Tennessee, the Southwest Region of Tennessee and Shelby County. In general, Shelby County has a lower incidence and a higher mortality for cancer for all sites. The table also shows that Shelby County has a higher incidence and mortality for female breast and prostate cancers than either the Southwest Region or the State of Tennessee.

8. Section B, Need, Item C.1 (Demographics)

What is the target population of the proposed project?

Response: The target population is the adult population 18 and older. For purposes of the information included in the application because of the way the population cohorts are defined, the target population is the adult population 20 and older, which would slightly underestimate the target population.

9. Section B, Need. Item E (Service Area Utilization)

The Shelby County linear accelerator utilization table on the bottom of page 30 is noted. However, the number of scanner column appears to be incorrect. According to the HSDA medical equipment registry, in 2016 a linear accelerator was transferred from the West Cancer Center to Methodist Healthcare-University Hospital. If so, the number of scanners for Methodist Healthcare-University Hospital should be "2/3". Please clarify and provide a corrected page 30 (labeled as 30R) if necessary.

Response: Please see corrected page 30, labeled as 30R and included as Attachment B, Need, Item E (Service Area Utilization).

10. Section B, Need. Item F

Provide the details regarding the methodology used to project utilization. The methodology **must include** detailed calculations or documentation from referral sources, and identification of all assumptions.

Response: The linear accelerators and the PET/CT are all existing scanners. They are among the highest utilized in the area. As such, they are almost fully utilized and do not have the capability to expand utilization significantly. Therefore, the applicant has anticipated that it will continue to provide essentially the same number of PET/CT scans and linear accelerator treatments in its first year of operation as it expects to provide in 2018.

11. Section B, Economic Feasibility Item B

Please provide a letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions.

Response: Please see letter from SunTrust Bank included as Attachment B, Economic Feasibility, Item B.

12. Section B, Economic Feasibility, Item D. (Projected Data Chart)

The Projected Data Chart for the linear accelerators and PET/CT are noted. However, please submit revised Projected Data Charts by revising rows D.1.a and D1. b. in each chart to reflect direct patient care and non-patient care totals and remove the total from line D.1.

Response: Please see revised Projected Data Charts included as Attachment B, Economic Feasibility, Item D, Projected Data Chart.

The PET/CT Projected Data Chart is noted. However, it is unclear how the applicant calculated the free cash flow totals in 2019 (\$1,699,132) and 2020 (\$1,7703,589) when there are no deductions from Net Income. Please clarify.

Response: Please see revised Projected Data Charts referenced above and included as Attachment B, Economic Feasibility, Item D, Projected Data Chart.

In each Projected Data Chart Line D.9 "Other Expenses" appears to be missing the related costs for FDG. Please clarify.

Response: The costs for FDG are included in the costs for supplies.

Please also identify the distance to the closest cyclotron source.

Response: The closest cyclotron source is located at 1388 Madison Ave., Memphis, 38104, approximately 15-20 miles away, depending on the driving route taken.

What are the arrangements for professional fees related to imaging interpretation services by radiologists? Are these reflected in the Projected Data Chart for the PET service?

Response: The radiologists are employed by West Clinic and the fees related to imaging/interpretation services are included in the Projected Data Charts under Physician's Salaries and Wages.

13. Section B, Economic Feasibility, Item E.1 (Average Gross Charge, Average Deduction from Operating Revenue, and Average Net Charge) and E.2 (Proposed Charges) and E.3

It is noted the applicant did not provide a Historical Data Chart. If so, please clarify how the applicant calculated the gross charge, deduction from Revenue, and average net charges for the Linear Accelerators and PET/CT?

Response: The applicant does not currently own and operate the equipment. However, as it is the group of physicians who operate the equipment, it was able to identify the gross charge, deduction from revenue and average net charge for the linear accelerators and the PET/CT.

The PET/CT chart on page 42 is noted. However, the Year 2 gross charge appears to be \$12,939 and the deduction from revenue \$10,869. Please clarify.

Response: The slight difference is because the numbers have been rounded.

It is noted upon the approval of this project and the implementation of the services as a physician office POS, the average net charge is expected to be approximately 16% less for linear accelerator services and 19% less for PET/CT services. For clarification purposes, what is the current charges under current ownership and proposed charges after the ownership change for the linear accelerator and PET/CT services?

Response: Please see page 42 which has the charts which identify the gross charge, the deduction from revenue, and the average net charge for the linear accelerators and the PET/CT for year one and year two after the initiation of services. As is shown on the chart, the average net charge for the linear accelerators is a little over 15% less (as opposed to the 16% listed above) and the average net charge for the PET/CT is approximately 19% less.

Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

Response: Please see information below for a comparison of charges for CPT codes for the linear accelerator and PET/CT services compared to the Medicare allowable fee schedule.

LINEAR ACCELERATOR		
CPT Code	Medicare Allowable (Tech)	Charge
77280	\$224.97	\$665.00
77417	\$10.24	\$478.00
77373	\$1,279.16	\$7,403.00
PET/CT		
CPT Code	Medicare Allowable (Tech)	Charge
78815	\$1,240.85	\$10,978.00

14. Section B., Economic Feasibility, Item F. (1), F.2., and F.3

Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For all projects, provide financial information for the corporation, partnership, or principal parties that will be a source of funding for the project. Copies must be inserted at the end of the application, in the correct alpha-numeric order and labeled as **Attachment Section B-Economic Feasibility-F1**. **NOTE: Publicly held entities only need to reference their SEC filings.**

Response: Please see copies of the balance sheet and income statement for the most recent time period included as Attachment B., Economic Feasibility, Item F.1. The West Clinic does not have audited financials.

The Net Margin Operating Ratio appears incorrect. Please recalculate the net margin operating ratio for Year One and Year Two of the proposed project.

Response: Please see revised page 43 included as Attachment B., Economic Feasibility, Item F.3.

Please calculate the capitalization ratio for the entity (applicant and/or parent company) that is funding the proposed project using the most recent year available from the funding entity's audited balance sheet, if applicable.

Response: The applicant does not have an audited balance sheet so is unable to perform this calculation.

15. Section B., Economic Feasibility, Item H.

The Germantown PET table on the top of page 46 is noted. However, please provide a total for Section A and submit a revised page 46.

Response: Please see revised page 46 included as Attachment B., Economic Feasibility, Item H.

16. Section B, Orderly Development, Item A.

List all existing health care providers (i.e., hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, that may directly or indirectly apply to the project, such as, transfer agreements, contractual agreements for health services.

Response: The applicant contracts with literally hundreds of payers or payer plans. Some of the major payers include CIGNA, Aetna, BCBS, Humana, United Healthcare, Coventry Health Care, Assurant, First Health and Liberty Mutual. In the unlikely event of an emergency, the applicant plans to have a transfer agreement with Methodist LeBonheur.

17. Section B, Orderly Development, Item D.

It is noted the applicant is accredited by ACR. What is ACR and please provide documentation of accreditation.

Response: The American College of Radiology provides accreditation for imaging services and has been recognized as the gold standard in medical imaging. Since 1987, the ACR has accredited more than 38,000 facilities in 10 imaging modalities.

ACR Accreditation helps assure patients that a facility provides the highest level of image quality and safety by documenting that the facility meets requirements for equipment, medical personnel and quality assurance.

A copy of the ACR accreditation certificates is included as Attachment B, Orderly Development, Item D.

18. Section B, Quality Measures

Please verify and acknowledge the applicant will be evaluated annually whether the proposal will provide health care that meets appropriate quality standards upon the following factors:

Response: In addition to satisfying the quality standards identified below, the applicant is in the process of discussing a collaborative effort to provide cancer care with prominent oncology groups in Tennessee and New York, as well as partners in technology and finance. The applicants feels that if this happens it will allow the practices to achieve certain synergies of scale and to collaborate on best practices as well as measurement of certain metrics. The venture will be a physician-driven, patient-centric, and technology-powered model aiming to transform cancer care delivery in America. The formation of this venture would not affect the ownership of The West Clinic and The West Cancer Center, but could possibly include the provision of management services to the West Clinic. The discussions are in the preliminary stages.

(3) Quality. Whether the proposal will provide health care that meets appropriate quality standards may be evaluated upon the following factors:

(a) Whether the applicant commits to maintaining staffing comparable to the staffing chart presented in its CON application;

Response: The applicant commits to providing staffing comparable to that included in the staffing chart in the CON application provided the utilization is also comparable to that provided in the application.

(b) Whether the applicant will obtain and maintain all applicable state licenses in good standing;

Response: The applicant will obtain and maintain any and all applicable state licenses in good standing.

(c) Whether the applicant will obtain and maintain TennCare and Medicare certification(s), if participation in such programs was indicated in the application;

Response: The applicant will continue to be a TennCare and Medicare provider.

(d) Whether an existing healthcare institution applying for a CON has maintained

substantial compliance with applicable federal and state regulation for the three years prior to the CON application. In the event of non-compliance, the nature of non-compliance and corrective action shall be considered;

Response: Not applicable. The applicant is not an existing healthcare institution.

(e) Whether an existing health care institution applying for a CON has been decertified within the prior three years. This provision shall not apply if a new, unrelated owner applies for a CON related to a previously decertified facility;

Response: Not applicable. The applicant is not an existing healthcare institution.

(f) Whether the applicant will participate, within 2 years of implementation of the project, in self-assessment and external assessment against nationally available benchmark data to accurately assess its level of performance in relation to established standards and to implement ways to continuously improve.

1. This may include accreditation by any organization approved by Centers for Medicare and Medicaid Services (CMS) and other nationally recognized programs. The Joint Commission or its successor, for example, would be acceptable if applicable. Other acceptable accrediting organizations may include, but are not limited to, the following:

(iv) American Society of Therapeutic Radiation and Oncology (ASTRO), the American College of Radiology (ACR), the American College of Radiation Oncology (ACRO), National Cancer Institute (NCI), or a similar accrediting authority, for Megavoltage Radiation Therapy projects;

(m) For Megavoltage Radiation Therapy projects, whether the applicant has demonstrated that it will meet the staffing and quality assurance requirements of the American Society of Therapeutic Radiation and Oncology (ASTRO), the American College of Radiology (ACR), the American College of Radiation Oncology (ACRO), National Cancer Institute (NCI), or a similar accrediting authority.

(v) American College of Radiology, for Positron Emission Tomography, Magnetic Resonance Imaging and Outpatient Diagnostic Center projects;

Response: The applicant anticipates continuing to be certified by the American College of Radiology and will meet its staffing and quality assurance requirements.

If you have any questions please contact me at Kim.Looney@wallerlaw.com or by telephone at 615-850-8722.

Sincerely,



Kim Harvey Looney

KHL:lag
Attachments

Attachment A, Project Details, Item 4.B

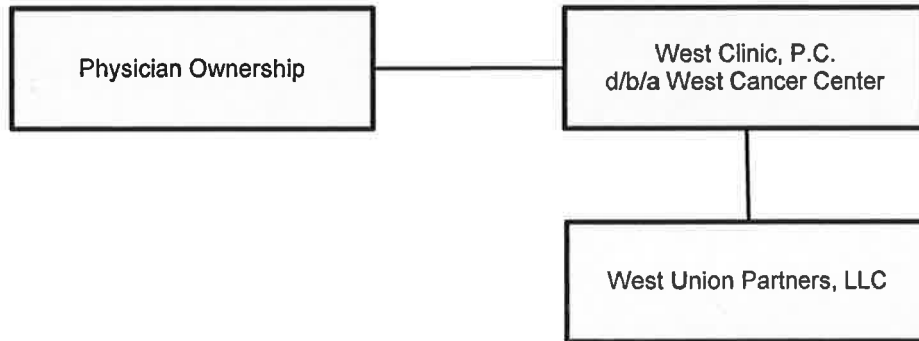
Physician Shareholders

Organizational Chart

**Shareholders with 5% or More Ownership & Managing Employees
08-21-2018**

Employee Name	Job Title
Baum, Scott L.	Radiologist
Benn, Sonia	Oncologist
Besh, Stephen A.	Oncologist
Chandler, Jason C.	Oncologist
Fenton, Moon	Oncologist
Martin, Michael G.	Oncologist
Pallera, Arnel M.	Oncologist
Portnoy, David	Oncologist
Powell, Daniel	Radiologist
Reed, Jarvis D.	Oncologist
Reed, Mark E.	Gyn Oncologist
Richey, Sylvia S.	Oncologist
Schwartzberg, Lee	Oncologist
Smiley, Linda M.	Gyn Oncologist
Somer, Bradley G.	Oncologist
Tauer, Kurt W.	Oncologist
Tian, Gang	Oncologist
Tillmanns, Todd	Gyn Oncologist
Vidal, Gregory A.	Oncologist
Wheeler III, Benton M.	Oncologist

**WEST CLINIC, P.C.
ORGANIZATIONAL CHART**



Attachment A, Project Details, Item 6.A

Executed Option to Purchase Agreement

Attachment A, Project Details, Item 6-B.2

Revised Floor Plan

Attachment A, Project Details, Item 13(F)

FDA Documentation



DEPARTMENT OF HEALTH & HUMAN SERVICES

Supplemental #1

August 29, 2018
Public Health Service
9:33 A.M.

AUG 1 2 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Elekta Limited
% Mr. Peter Stegagno
Director, Regulatory Affairs
& Quality Assurance
Elekta, Inc.
4775 Peachtree Industrial Boulevard
Building 300, Suite 300
NORCROSS GA 30092

Re: K051932
Trade/Device Name: Elekta Synergy®, Elekta Synergy® S
and XVI R3.5
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle
radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 8, 2005
Received: July 13, 2005

Dear Mr. Stegagno:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

August 29, 2018

9:33 A.M.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

August 29, 2018

9:33 A.M.

Indications for Use

510(k) Number (if known): K051932

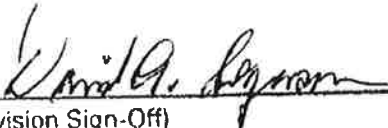
Device Name Elekta Synergy[®], Elekta Synergy[®] S, and XVI R3.5

Indication for Use: The Elekta Synergy[®], Elekta Synergy[®] S, and XVI R3.5 are intended to be used for radiation therapy treatment of malignant neoplastic diseases, as determined by a licensed physician.

Prescription Use - YES AND/OR Over-The-Counter Use - NO
(Per 21 CFR 801.109 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051932

AUG 1 2 2005

K051932

510(k) SUMMARY

Date of preparation of summary:

4th July 2005

Submitted by:

Elekta Limited
Linac House, Fleming Way
Crawley, West Sussex
RH20 9RR
United Kingdom

Contact name, (application correspondent):

Peter Stegagno, Director, Regulatory Affairs & Quality Assurance
4775 Peachtree Industrial Boulevard, Building 300, Suite 300
Norcross, Georgia, 30092
USA

Email: peter.stegagno@elekta.com

Telephone: (770) 300 9725 x2548

Fax: (770) 448 6338

Trade Name:..... Elekta Synergy[®], Elekta Synergy[®] S, and XVI R3.5

Common Name: Medical Linear Accelerator (with Patient Imaging)

Classification Name: Medical Linear Accelerator Accessory 90 IYE

Predicate Device: Elekta Synergy[®] System (K032996)

Product Description:

This Premarket Notification Special 510(k) describes modifications to the Elekta Synergy[®] System; a combination of the specially prepared Elekta medical linear accelerator, Elekta Synergy[®] Platform, with the XVI on-board kV imaging accessory. The primary reasons for the modifications to this product are to provide:

- ◆ Hardware & software support for increased patient throughput
- ◆ Easier selection of parameters & provision of clinical presets to improve efficiency
- ◆ Improved image quality and image management
- ◆ Improved tools for device set-up and image processing
- ◆ Improved connectivity with other systems through DICOM

Intended Use Statement:

This is unchanged from the predicate device and is defined as;
"The Elekta Synergy[®], Elekta Synergy[®] S, and XVI R3.5
are intended to be used for radiation therapy treatment of malignant neoplastic diseases, as determined by a licensed medical practitioner."

Summary of Technological Characteristics:

The Elekta Synergy[®] and Elekta Synergy[®] S comprise a standard Elekta medical linear accelerator, modified to accept the fitting of a kV imaging system (XVI R3.5), with a common MV and kV isocentre and orthogonal beam paths, all as previously cleared under Control Number K032996.

Supplemental #1

August 29, 2018

9:33 A.M.

There has been no change made to the underlying technological characteristics of the product.

August 29, 2018

9:33 A.M.

Public Health Service



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 4, 2013

Patrick Hull
Regulatory Affairs Specialist
Elekta Limited
Linac House
Fleming Way
CRAWLEY, WEST SUSSEX RH10 9RR
UNITED KINGDOM

Re: K123808
Trade/Device Name: Agility™
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: March 6, 2013
Received: March 7, 2013

Dear Mr. Hull:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

August 29, 2018

9:33 A.M.

Page 2—Mr. Hull

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Michael J. Hara". The signature is stylized with a large, looped "H" and "A".

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123808

Device Name: Agility™

Indications for Use:

The Agility multileaf collimator is indicated for use when additional flexibility is required in conforming the radiation beam to the anatomy to be exposed.

The associated Integrity R3.1 software is the interface and control software for the Elekta medical digital linear accelerator and is intended to assist a licensed practitioner in the delivery of radiation to defined target volumes (e.g. lesions, arterio-venous malformations, malignant and benign tumors), whilst sparing surrounding normal tissue and critical organs from excess radiation.

Both High Dose Rate mode and flattened beams are intended to be used for single or multiple fractions, delivered as static and/or dynamic, in gated or un-gated deliveries, in all areas of the body where such treatment is indicated.

The use of the Agility multileaf collimator in conjunction with an Elekta digital linear accelerator may be helpful in the delivery of radiation for treatment that includes but is not limited to malignant and benign brain tumors, brain metastases, spine lesions treated using SRS, squamous cell carcinoma of the head and neck, lung, breast, pancreatic, hepatic malignancies treated using SBRT, prostate, and bone metastases.

Prescription Use YES
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use NO
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign Off)

Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K123808

K 123808

510(k) SUMMARY

APR 04 2013

Date of preparation of summary: 14th February 2013

Submitted by:

Elekta Limited
Linac House, Fleming Way, Crawley, West Sussex
RH10 9RR, United Kingdom
Telephone: +44 (0)1293 654165 Fax: +44 (0)1293 658445

Contact name: Patrick Hull

Trade Name: Agility™

Common Name: Multileaf Collimator

Classification Name: Medical Linear Accelerator Accessory, 21CFR 892.5050

Product Code: IYE

Predicate Devices: Agility™ (K121328), Varian RPM (983629), Varian TrueBeam Linear Accelerator (K111106)

Product Description:

This Traditional 510(k) describes changes to the Elekta range of medical linear accelerators when fitted with the Agility multileaf collimator and associated Integrity linac control system. Items added are; High Dose Rate mode x-rays, specific clinical indications for use, and the Response™ gating interface that enables the linac treatment beam to be automatically turned on and off by signals from an external gating device.

High Dose Rate mode x-rays are provided by changes to the filtering arrangement to reduce wasteful attenuation of the beam.

Indications for Use and Intended Use Statement:

The Agility multileaf collimator is indicated for use when additional flexibility is required in conforming the radiation beam to the anatomy to be exposed.

The associated Integrity R3.1 software is the interface and control software for the Elekta medical digital linear accelerator and is intended to assist a licensed practitioner in the delivery of radiation to defined target volumes (e.g. lesions, arterio-venous malformations, malignant and benign tumors), whilst sparing surrounding normal tissue and critical organs from excess radiation.

Both High Dose Rate Mode and flattened beams are intended to be used for single or multiple fractions, delivered as static and/or dynamic, in gated or un-gated deliveries, in all areas of the body where such treatment is indicated.

The use of the Agility multileaf collimator in conjunction with an Elekta digital linear accelerator may be helpful in the delivery of radiation for treatment that includes but is not limited to malignant and benign brain tumors, brain metastases, spine lesions treated using SRS, squamous cell carcinoma of the head and neck, lung, breast, pancreatic, hepatic malignancies treated using SBRT, prostate, and bone metastases.

Summary of Technological Characteristics:

The Elekta range of medical linear accelerators when fitted with the Agility multileaf collimator beam limiting device and its associated linear accelerator control software, Integrity R3.1, and the addition of High Dose Rate mode x-rays and a gating interface do not introduce any novel forms of technology.

Substantial Equivalence

The functionality of the Elekta medical linear accelerator with Agility™ and High Dose Rate mode is substantially equivalent to that of its predicate device, Agility (K121328), in safety and effectiveness. The intended use, principles of operation, technological characteristics and labeling are substantially equivalent except for the addition of a number of specific indications for use.

Substantial Equivalence Table for High Dose Rate Mode

The primary functional differences between the predicate device and the new device are the changes made to the linac control software and beam filtration to allow the user the option to select unflattened x-ray beams in High Dose Rate mode and the option to fit a gating interface upgrade kit to permit external gating devices to temporarily suspend beam delivery.

Attributes	Elekta linac with Agility, FFF & Integrity R3.1 (this submission)	Varian TrueBeam Linear Accelerator (K111106)
Physics Performance		
Average transmission through leaf bank	<0.375%	Interleaf <2%
Peak transmission through leaf bank	<0.5%	Interleaf <3%
X-radiation leakage in patient plane outside collimator cone	<0.2% max, <0.1% avg.	Information not available
X-radiation leakage outside patient plane	<0.5% (at 1 m)	Information not available
Delivery Techniques		
Dynamic Delivery Capability, sliding window	yes	yes
Dynamic Delivery Capability, Dynamic arc	yes	yes
Dynamic Delivery capability, VMAT	yes	Yes (Rapid Arc)
Multiple island shielding	yes	yes
Offset field shaping	yes	yes
Beam Data – unflattened beams		
6MV - Minimum dose rate	200 MU/min	Not known
6MV - Maximum dose rate	1400 MU/min	1400 MU/min
10MV - Minimum dose rate	400 MU/min	Not known
10MV - Maximum dose rate	2200 MU/min	2400 MU/min

Substantial Equivalence Table for Response Gating Interface

The functionality of the Elekta medical linear accelerator with Agility™ and the Response gating Interface is substantially equivalent to that of its predicate device, RPM Respiratory Gating System (K983629), in safety and effectiveness. The intended use, principles of operation, technological characteristics and labeling are substantially equivalent except for the addition of a number of specific indications for use.

Attributes	Elekta linac with Response™ (this submission)	Varian RPM with gating of a Clinac (K983629)
Components		
Control module in the control room for enabling or disabling automated gating and for status review	yes	yes
Relay module on the linac	yes	equivalent
Electrically isolated connection between the Relay module on the linear accelerator and the Control module in the Control room	yes	unknown

Additional features		
<i>Protection for the linear accelerator against rapid gating cycles that may result in delivery of a radiation beam that does not meet IEC specification</i>	yes	unknown
<i>The latency of the signal transmission from the external gating device to operation of the Relay Module</i>	≤40 ms	unknown
Automated gating methods supported		
<i>Support external gating device for Respiratory Breath-Hold gating</i>	yes	yes
<i>Support external gating device for Exception gating</i>	Yes *	No **
<i>Support external gating device for Free-Breathing gating</i>	Yes *	No **
Delivery Techniques		
<i>3D Conformal</i>	Yes	Yes
<i>Intensity Modulated Radiation Therapy (IMRT)</i>	Yes	Yes
<i>Image Guided Radiation Therapy (IGRT)</i>	Yes	Yes
<i>Dynamic Delivery Capability, sliding window</i>	Yes	Unknown
<i>Dynamic Delivery Capability, dynamic arc</i>	Yes	Unknown
<i>Dynamic Delivery Capability, VMAT</i>	Yes	Unknown
<i>High Dose Rate (unflattened beams)</i>	yes	Unknown

* with validated external gating device which has 510(k) clearance

** other methods are not supported with the RPM interface

Summary of non clinical performance testing

Testing in the form of module, integration and system level verification was performed to evaluate the performance and functionality of the new and existing features against the requirement specification.

Regression testing has been performed successfully to verify the integrity of any changes.

Validation of the system under clinically representative conditions has been performed by competent and professionally qualified personnel. Results from verification and validation testing demonstrate that conformance to applicable technical design specifications have been met and assured safety & effectiveness as been achieved.

Testing has been undertaken on production equivalent systems both at Elekta and at hospital sites.

The system is subject to compliance testing to voluntary consensus safety standards. Details of the standards employed in the design are specified in the Standard Data Report in section 9 which includes but is not limited to, IEC 60601-1, IEC 60601-2-1, IEC 62304, IEC 62366 and ISO 14971.

**Attachment B, Need, Item 1 (Project Specific Criteria-MRT
Service)**

MRT Documentation

August 29, 2018

9:33 A.M.

August 27, 2018

West Clinic
7945 Wolf River Blvd
Germantown, TN 38138
Attention: Hartwell Strain

Dr. Mr. Strain,

Per our discussions, I wanted to provide you a letter to cover the fact that during the renovations in 2010 at the above referenced address I was able to coordinate with the contractor to come visually inspect the installation of the lead shielding called for in the room designs, which I copied you today. I was also able to do the same for the recent changes made to part of the uptake room walls in 2017, which were necessary due to a change in usage of adjacent space. The lead in these rooms met with those specifications and in fact in other parts of your radiology space deficiencies were noted and corrected immediately. Those problems may or may not have been caught with a simple after the fact radiographic survey of a closed set of walls. If you feel you need me to test the walls attenuation with a radioactive source I could do that as part of my father and my radioactive license, but I would think this is not necessary. Please let me know if you have any further questions, and keep in mind that if usage, workload or adjacent occupancies change the current shielding will need to be re-evaluated as it was in 2017, and this includes new equipment installations.



Thaddeus A. Wilson, Ph.D., DABR, FAAPM
Registered Inspector 2058
5150 Shady Grove Rd.
Memphis, TN 38117

August 29, 2018

9:33 A.M.

November 11, 2013

Mr. Erich Mounce
Chief Executive Officer
West Cancer Center
100 Humphreys Blvd.
Memphis, TN 38120

RE: VERIFICATION OF CONSTRUCTION COST ESTIMATE -
WEST CANCER CENTER, MEMPHIS, TENNESSEE

Dear Mr. Mounce:

We have reviewed the construction cost estimates and descriptions for the project in the CON packet and compared them to typical construction costs we have experienced in the Mid South region for healthcare construction.

It is brg3s's opinion, that in today's dollar the projected \$19.2 million construction budget is consistent with the cost value for this type of construction and similar projects in this market. The budget includes \$15.7 million for construction, \$0.48 million for site work, \$1.6 million design/A&E fees and \$1.8 million for contingency. While specific finish choices and market conditions can greatly affect the cost of any project, the costs assumed in the estimate appear adequate for mid range finishes used in a healthcare environment for the scope of work for the West Cancer Center.

In providing opinions of probable construction cost, the Client understands the Consultant has no control over the cost or availability of labor, equipment or material, or over market conditions or the Contractor's method of pricing and that the Consultant's opinions of probable construction costs are made on the basis of the Consultants professional judgment and experience. The consultant makes no warranty, express or implied, that the bids or the negotiated cost of the work will not vary from the Consultant's opinion of probable construction cost.

This facility includes PET Scanner, MRI, CT and Linear Accelerators and will be designed in accordance with all applicable federal and state standards, regulations and guidelines, licensing agency requirements and with equipment manufacturer's specifications at the proposed location of the West Cancer Center, Wolf River Blvd., Germantown, TN.

Please do not hesitate to contact us if you require any additional information.

Sincerely,

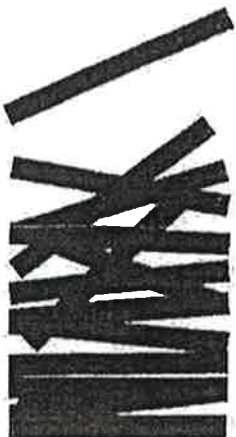
brg3s



Jon R. Summers, AIA
Principal

11 W. Huling Avenue
Memphis, Tennessee 38103
t 901.260.9600
f 901.531.8042
w brg3s.com

brg3s



August 29, 2018**9:33 A.M.**

July 11, 2017

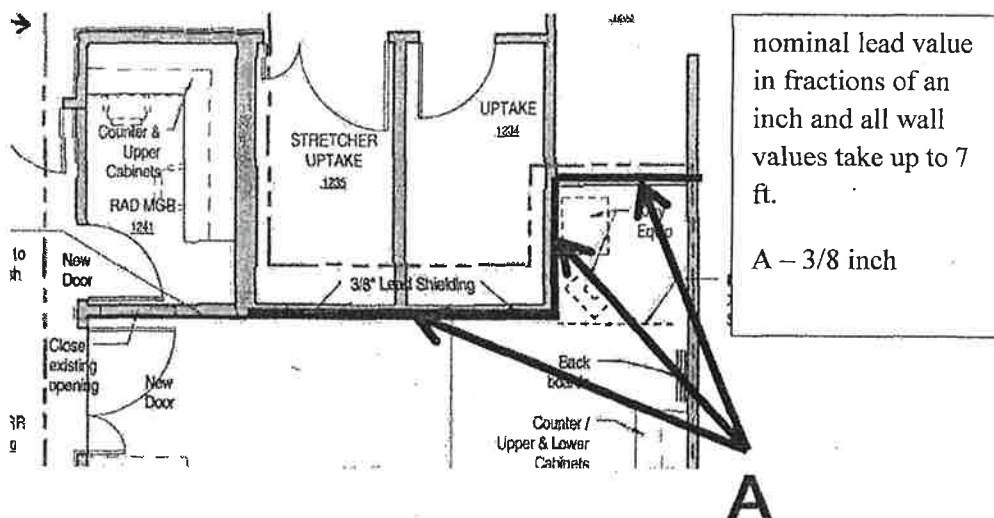
Dear Mr. Eddie Manning, Construction Project Management

RE: West Clinic space modification involving uptake rooms (Wolf River Blvd) replaces report/memo dated 7/10/2017

This report/memo is in reference to your request for a shielding evaluation for a proposed modification to the adjacent space to the existing PET uptake rooms in diagram below. Please find below a copy of the proposed space and some of the given data used to recalculate shielding requirements for this wall. The methodology in AAPM task group report 108 on PET and PET/CT shielding design was used and variable descriptions can be found in that reference.

1. Number of patients is 50/week divided evenly between the three uptake rooms.
2. Average dose of 555 MBq
3. $R_{tu}=0.83$ (Reduction factor for F-18 for 60 min)
4. Uptake time 1 hour
5. Radiographic/Interventional space design goals
 - a. $T=0.5$ for treatment room and $T=1$ for control booth taken from NCRP 147 (occupancy values including the control booth as it was indicated some radiology staff might spend some time in that space other than for operation of the fixed radiographic controls) Note that currently the two walls adjacent to the control booth have $1/4"$ lead on the inside of those rooms and originally this was just a radiographic room which was not utilized significantly.
 - b. $P=100 \mu\text{Sv}$ (weekly controlled area dose limit)

An additional $3/8"$ lead will be needed on the walls abutting the uptake rooms. Additional nominal lead values taken up to at least 7 ft. This is in addition to the existing $1/16"$ lead on the long wall with 1235 and 1234 and $1/4"$ on 1234 and 1233 abutting the control booth.

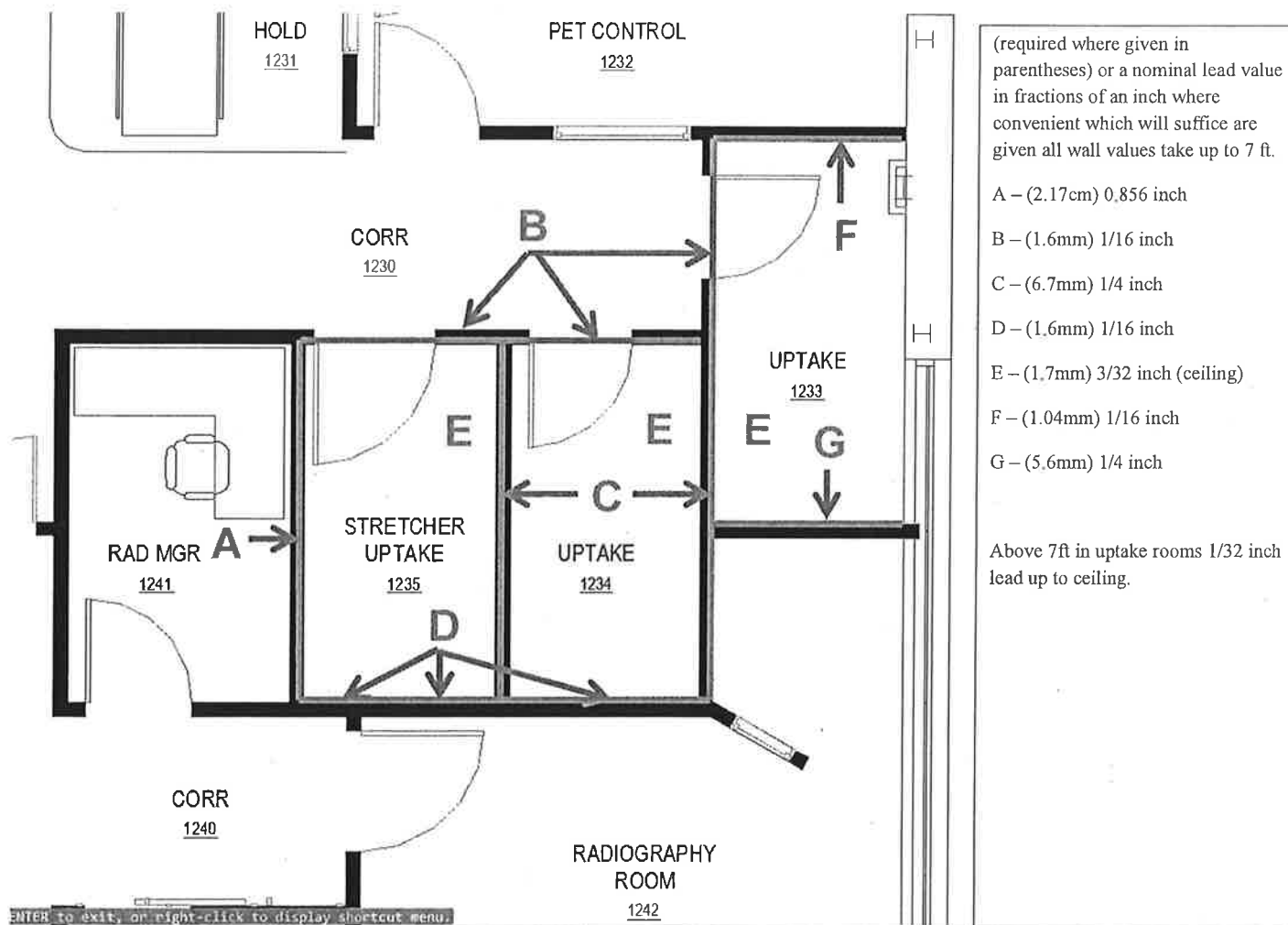


Submitted by:

Thaddeus A. Wilson, PhD, DABR (Diagnostic and Nuclear Physics)

5150 Shady Grove Rd.

Memphis, TN 38117



Supplemental #1

August 29, 2018

9:33 A.M.

(required where given in parentheses) or a nominal lead value in fractions of an inch where convenient which will suffice are given take all walls up to 7 ft.

A – (0.65mm) 1/32 inch

B – (0.37mm) 1/32 inch

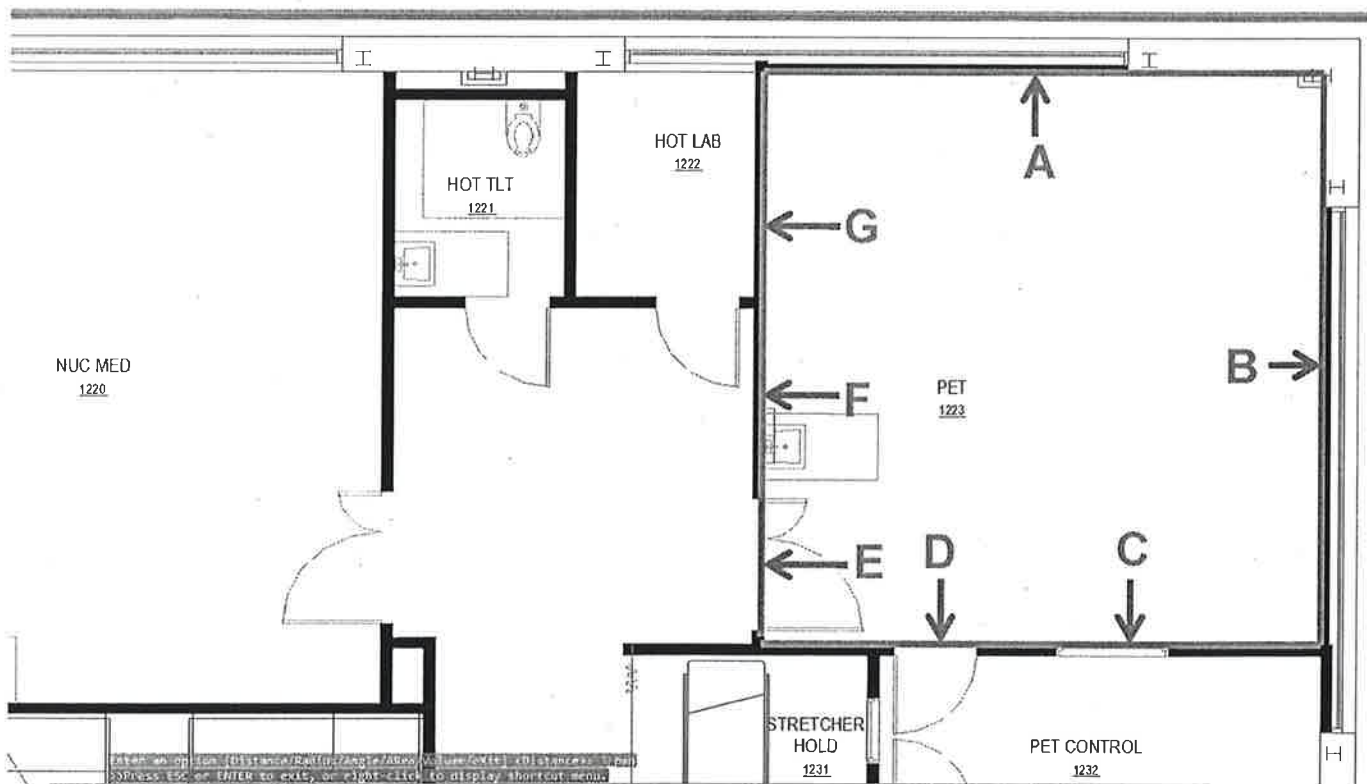
C – (1.3mm) 1/16 inch

D – 1/32 inch

E – (0.415mm) 1/32 inch

F – (1.25mm) 1/16 inch

G – (6.15mm) 1/4 inch



**Attachment B, Need, Item 1, 6(b) (Project Specific Criteria-
PET Service)**

PET Conforming Documentation

August 29, 2018


9:33 A.M.

August 27, 2018

West Clinic
7945 Wolf River Blvd
Germantown, TN 38138
Attention: Hartwell Strain

Dr. Mr. Strain,

Per our discussions, I wanted to provide you a letter to cover the fact that during the renovations in 2010 at the above referenced address I was able to coordinate with the contractor to come visually inspect the installation of the lead shielding called for in the room designs, which I copied you today. I was also able to do the same for the recent changes made to part of the uptake room walls in 2017, which were necessary due to a change in usage of adjacent space. The lead in these rooms met with those specifications and in fact in other parts of your radiology space deficiencies were noted and corrected immediately. Those problems may or may not have been caught with a simple after the fact radiographic survey of a closed set of walls. If you feel you need me to test the walls attenuation with a radioactive source I could do that as part of my father and my radioactive license, but I would think this is not necessary. Please let me know if you have any further questions, and keep in mind that if usage, workload or adjacent occupancies change the current shielding will need to be re-evaluated as it was in 2017, and this includes new equipment installations.


Thaddeus A. Wilson, Ph.D., DABR, FAAPM
Registered Inspector 2058
5150 Shady Grove Rd.
Memphis, TN 38117

August 29, 2018

9:33 A.M.

November 11, 2013

Mr. Erich Mounce
Chief Executive Officer
West Cancer Center
100 Humphreys Blvd.
Memphis, TN 38120

RE: VERIFICATION OF CONSTRUCTION COST ESTIMATE -
WEST CANCER CENTER, MEMPHIS, TENNESSEE

Dear Mr. Mounce:

We have reviewed the construction cost estimates and descriptions for the project in the CON packet and compared them to typical construction costs we have experienced in the Mid South region for healthcare construction.

It is brg3s's opinion, that in today's dollar the projected \$19.2 million construction budget is consistent with the cost value for this type of construction and similar projects in this market. The budget includes \$15.7 million for construction, \$0.48 million for site work, \$1.6 million design/A&E fees and \$1.6 million for contingency. While specific finish choices and market conditions can greatly affect the cost of any project, the costs assumed in the estimate appear adequate for mid range finishes used in a healthcare environment for the scope of work for the West Cancer Center.

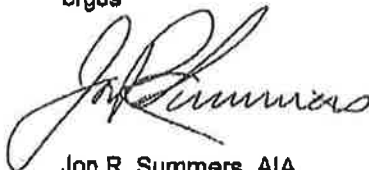
In providing opinions of probable construction cost, the Client understands the Consultant has no control over the cost or availability of labor, equipment or material, or over market conditions or the Contractor's method of pricing and that the Consultant's opinions of probable construction costs are made on the basis of the Consultants professional judgment and experience. The consultant makes no warranty, express or implied, that the bids or the negotiated cost of the work will not vary from the Consultant's opinion of probable construction cost.

This facility includes PET Scanner, MRI, CT and Linear Accelerators and will be designed in accordance with all applicable federal and state standards, regulations and guidelines, licensing agency requirements and with equipment manufacturer's specifications at the proposed location of the West Cancer Center, Wolf River Blvd., Germantown, TN.

Please do not hesitate to contact us if you require any additional information.

Sincerely,

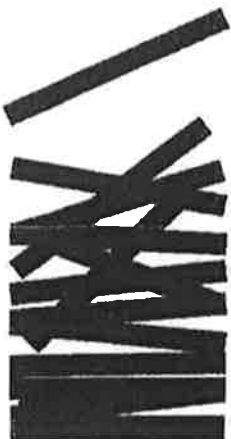
brg3s



Jon R. Summers, AIA
Principal

11 W. Huling Avenue
Memphis, Tennessee 38103
t 901.260.9600
f 901.531.8042
w brg3s.com

brg3s



August 29, 2018**9:33 A.M.**

July 11, 2017

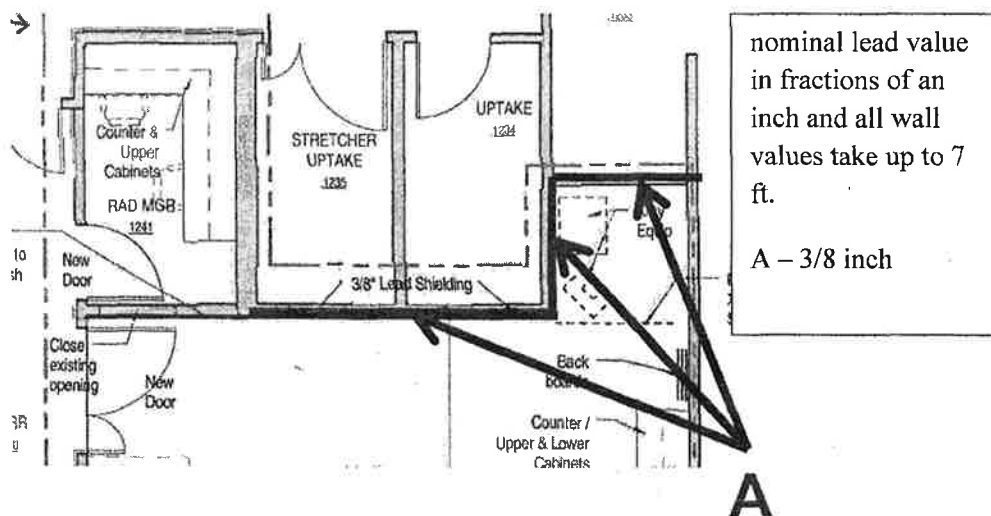
Dear Mr. Eddie Manning, Construction Project Management

RE: West Clinic space modification involving uptake rooms (Wolf River Blvd) replaces report/memo dated 7/10/2017

This report/memo is in reference to your request for a shielding evaluation for a proposed modification to the adjacent space to the existing PET uptake rooms in diagram below. Please find below a copy of the proposed space and some of the given data used to recalculate shielding requirements for this wall. The methodology in AAPM task group report 108 on PET and PET/CT shielding design was used and variable descriptions can be found in that reference.

1. Number of patients is 50/week divided evenly between the three uptake rooms.
2. Average dose of 555 MBq
3. $R_{tu}=0.83$ (Reduction factor for F-18 for 60 min)
4. Uptake time 1 hour
5. Radiographic/Interventional space design goals
 - a. $T=0.5$ for treatment room and $T=1$ for control booth taken from NCRP 147 (occupancy values including the control booth as it was indicated some radiology staff might spend some time in that space other than for operation of the fixed radiographic controls) Note that currently the two walls adjacent to the control booth have 1/4" lead on the inside of those rooms and originally this was just a radiographic room which was not utilized significantly.
 - b. $P=100 \mu\text{Sv}$ (weekly controlled area dose limit)

An additional 3/8" lead will be needed on the walls abutting the uptake rooms. Additional nominal lead values taken up to at least 7 ft. This is in addition to the existing 1/16" lead on the long wall with 1235 and 1234 and 1/4" on 1234 and 1233 abutting the control booth.

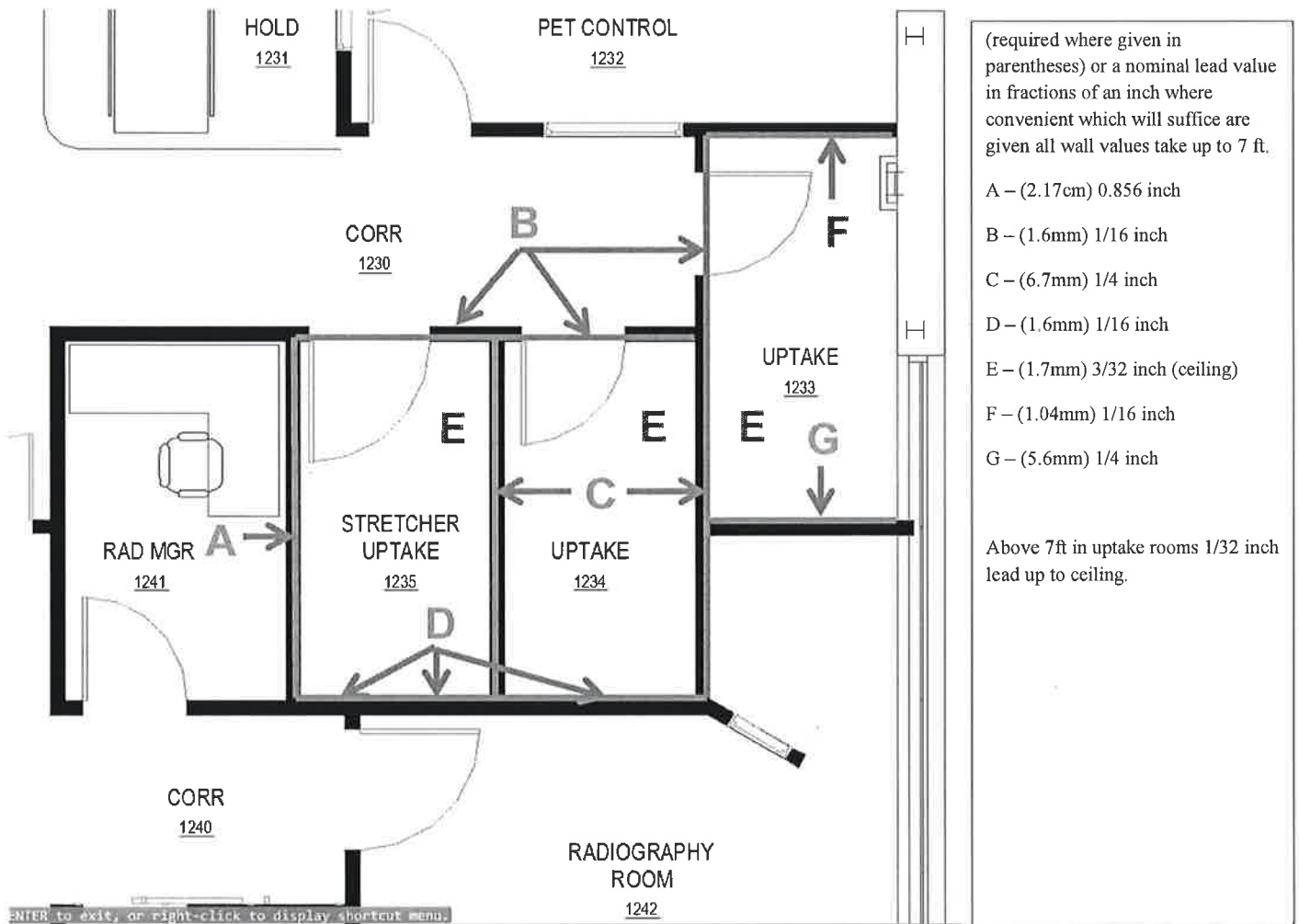


Submitted by:

Thaddeus A. Wilson, PhD, DABR (Diagnostic and Nuclear Physics)

5150 Shady Grove Rd.

Memphis, TN 38117



Supplemental #1

August 29, 2018

9:33 A.M.

(required where given in parentheses) or a nominal lead value in fractions of an inch where convenient which will suffice are given take all walls up to 7 ft.

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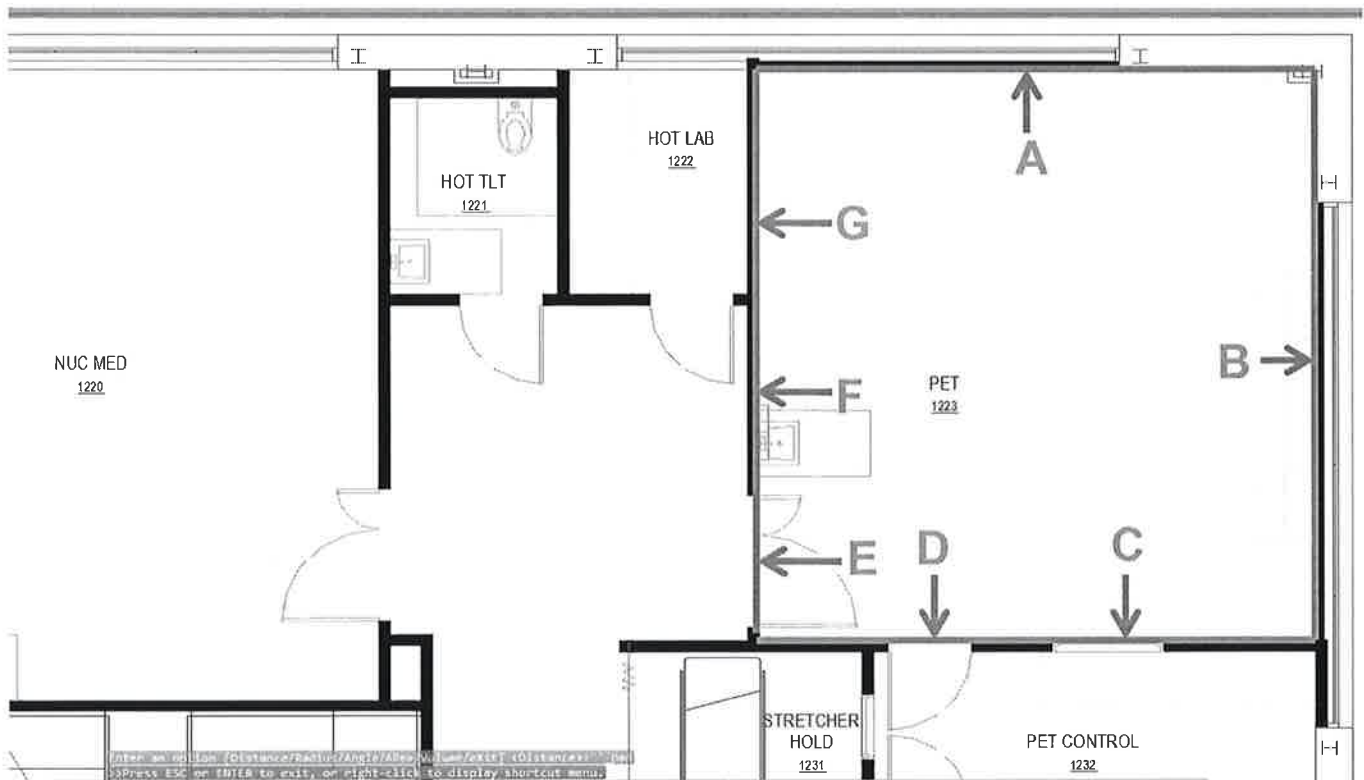
C – (1.3mm) 1/16 inch

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**Attachment B, Need, Item 1, 6(d)
(Project Specific Criteria-PET Service)**

PET Policies

WEST CANCER CENTER

Created: January, 2016

Reviewed: January 2017

Authorized: Hartwell Strain, Radiology Director, 1-21-17

POLICY ON: *Radiologist Peer Review Program*

In an effort to improve organizational-wide quality, reduce errors and promote a culture of safety, the Department of Radiology at West Cancer Center participates in an alternative radiologist peer review program. The peer review program consists of:

- A. The imaging study will be interpreted by 2 MDs.
- B. Each reading radiologist is expected to peer review at least 10 cases per month.
- C. Cases reviewed should be representative of the actual clinical practice of each radiologist
- D. The reviewer should assess the agreement of the original report with subsequent review to determine if there are additional or different findings not identified.
- E. The reviewer should classify peer review findings with regard to the level of quality concerns according to the scoring system as seen below, using the peer review form:
 - 1 = Concur with Interpretation
 - 2 = Discrepancy in Interpretation/not ordinarily expected to be made (Understandable miss)
 - 3 = Discrepancy in Interpretation/should be made most of time
 - 4 = Discrepancy in Interpretation/should be made almost every time-misinterpretation of findings
- F. Of any discrepant peer review findings of a score of 3 or 4, the imaging study will be reviewed by the Quality Improvement Committee (QIC) and/or delegate to confirm that there was a miss and clinical significance. If confirmed:
 - a. The reviewer will document the discrepancy in detail on the peer review form.
 - b. An addendum will be added to the report to reflect missed significant findings.
 - c. The original ordering provider will get updated via email.
 - d. If significantly warranted, a report will be sent to the Chairman of Radiology for appropriate corrective measures.
- G. On a quarterly basis:
 - a. Summary statistics and comparison will be generated, for each radiologist, by modality and facility.
 - b. Review statistics will be sent to each radiologist for their review.
 - c. These results will be reviewed by the QIC for any of the above mentioned actions if necessary.

QIC Peer Review Worksheet

Instructions: Please print your name and the date the worksheet was completed in the boxes provided. Include the medical record number, name of the reviewing physician, the date the study was performed, and identify the type of study in the space provided.

Peer Reviewer:

Month Completed:

Patient's Name/ MRN	Name of Original Reader	Date of Procedure	Type of Study	I	II	III *	IV *	Indication for Exam Reviewed Yes/No	Correlation with Prior Images Yes/No/NA
			CT					Y N	Y N NA
			CT					Y N	Y N NA
			CT					Y N	Y N NA
			CT					Y N	Y N NA
			CT					Y N	Y N NA
			CT					Y N	Y N NA
			CT					Y N	Y N NA
			CT					Y N	Y N NA
			CT					Y N	Y N NA
			CT					Y N	Y N NA
			CT					Y N	Y N NA
			CT					Y N	Y N NA
			CT					Y N	Y N NA
			CT					Y N	Y N NA
			CT					Y N	Y N NA
			CT					Y N	Y N NA

I Concur with interpretation

II Difficult diagnosis, not ordinarily expected to be made

*III Diagnosis should be made most of the time

*IV Diagnosis should be made almost every time - misinterpretation of finding

***All category III or IV discrepancies must be detailed and attached to this form.**

Our discussions, materials and commentary are only occurring with the expectation of absolute confidentiality and in accordance with the rules of our Quality Improvement Committee.

QIC Peer Review Worksheet

Instructions: Please print your name and the date the worksheet was completed in the boxes provided. Include the medical record number, name of the reviewing physician, the date the study was performed, and identify the type of study in the space provided.

Peer Reviewer:

Month Completed:

Patient's Name/ MRN	Name of Original Reader	Date of Procedure	Type of Study	I	II	III *	IV *	Indication for Exam Reviewed Yes/No	Correlation with Prior Images Yes/No/NA
			PET					Y N	Y N NA
			PET					Y N	Y N NA
			PET					Y N	Y N NA
			PET					Y N	Y N NA
			PET					Y N	Y N NA
			PET					Y N	Y N NA
			PET					Y N	Y N NA
			PET					Y N	Y N NA
			PET					Y N	Y N NA
			PET					Y N	Y N NA
			PET					Y N	Y N NA
			PET					Y N	Y N NA
			PET					Y N	Y N NA
			PET					Y N	Y N NA
			PET					Y N	Y N NA

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***All category III or IV discrepancies must be detailed and attached to this form.**

Our discussions, materials and commentary are only occurring with the expectation of absolute confidentiality and in accordance with the rules of our Quality Improvement Committee.



Effective Date: 03/18/2016

Radiology Director Signature: _____

PURPOSE

To maximize quality of diagnostic information and to minimize patient, personnel, & public risk

RESPONSIBILITIES

The quality control program is under the supervision of the Director or Manager of each Radiology area. This individual shall have the responsibility of establishing and maintaining the quality control program for that area. She/he may delegate specific tasks to other members of the department, but shall retain full responsibility for:

- Maintaining the program
- Ensuring that appropriate documentation of operation is performed
- Ensuring that maintenance on all equipment is completed

SAFETY

Safety to patients, personnel, and the public are important parts of quality control. Radiology safety policies & procedures may be found in various hospital/system manuals such as the:

Environment of Care Manual

- Internal & External Disaster Manual
- Infection Control Manual
- Hazardous Material & Waste Management Manual
- Systems Policy Manual
- Management Manual

PROPER PERFORMANCE OF EQUIPMENT

1. Equipment used in the diagnosis, treatment, or monitoring of patients shall be properly maintained to ensure proper performance and safety.
2. Minor electrical support equipment in the Radiology areas (e.g., safelights, view boxes, lamps, etc.) is inspected, both visually and for electrical leakage annually by Clinical Engineering. Problems are documented and reported to Clinical Engineering and/or Vendor service representative for repair. Records for these tests are maintained in Clinical Engineering.
3. Regularly schedule **preventive maintenance of equipment** is performed for major Radiographic/Imaging equipment according to the following schedule:

August 29, 2018

Type of Equipment	Preventive Maintenance	Physician Review
Radiographic Rooms	Annually	Annually
C-Arm Equipment	Annually	Annually
Ultrasound Units	Annually	As needed
CT Equipment	Annually	Annually
MRI Equipment	Annually	Annually
PET/CT Equipment	Annually	Annually

EQUIPMENT TRAINING/ORIENTATION

- Before new staff members are expected to work on equipment, an orientation with another staff member is given. They rotate through rooms with a knowledgeable technologist.
- Operating instructions for each piece of equipment may be located in the department, Radiology Engineering, or found on the Radiology Share Drive
- After explanation/demonstration of equipment and verbal confirmation by employee of understanding, an initial departmental competency and training form is completed by Manager/Supervisor or by the designated staff member giving the orientation.
- Staff members may not utilize equipment that has not been properly explained/demonstrated to them.
- When new equipment is installed or major modification is made, the training shall be provided by vendor. All employees will be trained on new/changed equipment before operating.
 - Training manuals shall be provided by vendor to include operating instructions and service manuals.
 - Training shall include operation, application and safety aspects of equipment.
 - Additional training will occur thereafter as deemed necessary by supervisors involved.
- Periodic training/re-orientation will be given on major pieces of equipment, if needed.

EVALUATION OF EQUIPMENT PERFORMANCE

- Minimum guidelines for evaluation of equipment performance by service engineers shall include the following:
 - Radiographic Systems-** kVp accuracy, timer accuracy, and mA linearity.
 - Fluoroscopic Systems-** High contrast and low contrast resolution tests, Radiation outputs for a standard patient thickness in the automatic brightness mode; maximum fluoroscopic a radiation outputs; cine dose rate for cardiac systems.
 - Computed Tomography-** Imaging performance data, e.g., identify noise level and resolution.
 - Ultrasound Systems-** Spatial and axial resolution penetration of each transducer. Power supply assemblies - check voltage and current. Clean entire system and camera. Check cables/connectors for proper seating.
 - MRI Systems-** Resolution and signal-to-noise ratio.
 - PET Systems-** Spatial resolution, sensitivity, scatter fraction, and count rate performance
- The remaining components of evaluation of equipment performance and quality control are performed by technical staff within the department:
 - CASSETTES/SCREENS or CR PLATES** - Visual inspection of screen or plate condition for defect/artifact identification. Regular cleaning of screens and or plates is performed.
 - LEAD APRONS, GLOVES AND THYROID SHIELDS-** Annual visual and radiographic testing of lead shielding devices to assure protection from radiation.

PHYSICIST EVALUATION OF EQUIPMENT, PROCEDURES, RADIATION SAFETY 9:33 A.M.

1. A qualified medical Radiation Physicist performs annual testing on all radiation-producing equipment in Radiology/CT/PET/MRI.
2. In Radiology/CT, the following test procedures are performed annually with results reported to the state of Tennessee, Division of Radiological Health:
 - a. **Radiographic/CT-** S.I.D. Indicator, Film/Beam Alignment, Automatic Collimation, Timer Accuracy, mR Reproducibility, Half-Value Layer (Filtration), Field Size Indicator, X-ray/Light Congruence, kVp Accuracy, Timer Reproducibility
 - b. **Fluoroscopic-** Fluoro Collimation, Barrier greater than beam, Timer, Table top outlet, Target to table top distance, Beam/Image Receptor Alignment, Barrier beam linkage, Half-Value Layer (Filtration)
3. The physicist also surveys to determine if compliance is met in the following:
 1. "Caution – Radiation..." signs are posted
 2. Technique charts posted
 3. Exposure cords appropriate length -unable to step outside control panel
 4. Battery powered machines – to be able to see status of battery charge
 5. Tubes using one exposure switch clearly indicated on control panel
 6. Tube heads unable to drift during exposures
 7. Permanent markings to indicate image receptor size and SID
 8. Tube registration present
 9. State regulations present
 10. "Notice to Employees" present
 11. X-ray Room" signs posted outside radiation-producing rooms
 12. Rooms have adequate shielding based on survey
 13. All personnel exposed to radiation have monitoring devices
 14. Personnel monitoring devices worn outside of apron at collar
 15. Personnel monitoring reports complete
 16. Personnel in or near the primary beam wear lead gloves
 17. Persons under 18 or pregnant women do not hold films/patients
 18. Gonadal shielding used during each exam in which gonads are in the useful beam except when
 19. All lead aprons/gloves' protective ability is not impaired
4. Provides all testing for the Nuclear Medicine Department and Radiation Therapy in accordance with State and Federal guidelines.
5. Advises facility on all matters regarding radiation.
6. Assists with developing all policies/procedures regarding radiation.
7. All new radiation producing equipment shall be inspected by Radiation Physicist before equipment is used on patients.
8. Radiation Protection File - Located in Radiology Department or Radiology Engineering
 - a. State Regulations Manual
 - b. Radiological Physics surveys
 - c. State X-Ray Tube Registrations
 - d. State Inspections and replies.
 - e. Radiation Badge reports.
 - f. Radiation shielding recommendations (from architect).
 - g. Glove and apron fluoro surveys (annual survey).



Effective Date: 03/18/2016

Medical Director Signature: _____

I. PURPOSE

To ensure safe and secure storage of radiopharmaceuticals

II. SCOPE

This policy applies to all employees and contractors that supply or handle radiopharmaceuticals for West Cancer Center, West Clinic, and other MLH facilities.

III. RESPONSIBILITIES

It is the responsibility of the Radiology Director to see that staff are properly trained upon hire and as directed through annual reorientation about safety and security policies surrounding the storage and handling of radiopharmaceuticals.

IV. PROCEDURE

1. Employees are trained upon initial orientation on the procedures within this policy
2. The radiopharmaceutical storage facility is secured through badge access.
3. Nuclear pharmacy delivery personnel are escorted to the hot lab by West/MLH Nuclear Medicine staff. After delivery, they are escorted out.
4. An inventory of all radiopharmaceuticals and all other radioactive sources is maintained.
5. If a discrepancy is observed, it is immediately reported to the Radiology Director, who initiates an investigation. This investigation includes any and all institutional and government bodies as required.

V. DESIRED OUTCOME

100% safe and secure storage of radiopharmaceuticals and other radioactive sources



Effective Date: 03/18/2016

Medical Director Signature: _____

I. INDICATIONS

- A. Differentiating benign from malignant lesions
- B. Searching for an unknown primary tumor when metastatic disease is discovered as the first manifestation of cancer or when the patient presents with a paraneoplastic syndrome
- C. Staging known malignancies
- D. Monitoring the effect of therapy on known malignancies
- E. Determining whether residual abnormalities detected on physical examination or on other imaging studies after treatment represent tumor or post-treatment fibrosis/necrosis
- F. Detecting tumor recurrence, especially in the presence of elevated levels of tumor markers
- G. Selecting the region of a tumor most likely to yield diagnostic information for biopsy
- H. Guiding radiation therapy planning

II. PROCEDURE

A. Patient Preparation:

- 1. Determine if female patient 55 years of age or younger are possibly pregnant or breastfeeding. If a patient is possibly pregnant, a pregnancy test is given prior to injection of FDG. Patients that are breastfeeding are advised to discontinue breastfeeding for 24 hours after the scan.
- 2. Before arrival, patients are instructed to fast, not consume beverages (except for water), and not smoke after midnight prior to the day of scan. Three 8 oz. cups of water are advised to keep the patient hydrated. Intravenous fluids containing dextrose or parenteral feedings should also be withheld 4-6 hours prior to injection of FDG. Patients scheduled in the afternoon may eat a light breakfast, providing they begin fasting 4-6 hours prior to injection of FDG. See "PET/CT SCAN INSTRUCTIONS" sheet for more patient instructions.
- 3. Before injection of FDG, glucose levels are checked to verify that a patient's glucose is below 200. **If glucose levels are above 200, the patient is rescheduled.** When intravenous contrast media is used, patients are screened for a history of iodinated contrast media allergy, use of metformin for treatment of diabetes, and renal disease (serum creatinine and GFR lab values).
- 4. Obtain patient's weight prior to injection of FDG.

B. Patient History

- 1. Focused history, including the type/site of malignancy, dates of diagnosis/treatment (biopsy results, surgery, radiation, chemotherapy, and administration of bone marrow stimulants or steroids), and current medications
- 2. History of diabetes, fasting state, and recent infection
- 3. Patient's ability to lie still for the duration of the acquisition (15-45 min)

4. History of claustrophobia (5 mg of Valium/diazepam is given to patients with drivers)
5. Patient's ability to put his/her arms overhead
6. See "PET/CT Work Sheet" for more patient history questions

III. INJECTION OF RADIOPHARMACEUTICAL

- A. The **ADULT dose range for ^{18}F -FDG is 5-20 mCi**. Low end of dose range should be considered for smaller patients. Administered activity may take into account patient mass and time available on PET scanner.
- B. The **PEDIATRIC dose range for ^{18}F -FDG is 0.10-0.14 mCi/kg with a minimum of 1 mCi**. Low end of dose range should be considered for smaller patients. Administered activity may take into account patient mass and time available on PET scanner.
- C. Calibration of the dose is measured and documented immediately pre and post injection for administered dose calculation value. The patient remains seated for administration of FDG and then remains seated/reclined during the uptake phase (60-90 min) in a dimly-lit holding room. Scan begins 60-90 min post injection. (See ^{18}F -FDG Package Insert for radiation dosimetry information.)
- D. Patients should be advised to not read, use a phone/tablet, or listen to music for the entirety of the uptake phase.

IV. IMAGE ACQUISITION

- A. Typical acquisition parameters are base of skull to the mid-thigh region. For tumors involving the scalp or lower extremities, total-body tumor imaging is performed (i.e. history of melanoma)
 1. Patient positioning and pre-acquisition preparation
 - a. Patient is instructed to void before acquisition to reduce radiation dose to the bladder.
 - b. All metallic objects are removed from the patient.
 - c. Arms are positioned over the head if patient is able to tolerate, otherwise arms are positioned along the side.
 2. Protocol for CT imaging
 - a. A low-dose scout CT is obtained for CT and PET imaging parameters.
 - b. A CT is obtained. To those patients with serum **creatinine levels lower than 2.0 mg/dL, GFR greater than or equal to 31, and no history of iodine allergy**, 100-115 mL of Omnipaque/Visipaque intravenous contrast is administered at a flow rate between 1.5-1.8 mL/sec.
 3. Protocol for PET imaging
 - a. Emission images are obtained 60-90 min post FDG injection.
 - b. The emission image acquisition time varies from 1.5-5 min per bed position, depending on the tumor site and patient body weight.

V. IMAGE PROCESSING

- A. PET Reconstruction
 1. PET data consist of the number of detected events along lines of response between detector pairs. The emission data is corrected for detector efficiency (normalization), system dead time, random coincidences, scatter, attenuation, and sampling nonuniformity. All of these corrections are incorporated directly into the computer's reconstruction process. The non-attenuation-corrected images are automatically

reconstructed in a 3D-RAMLA, and the attenuation-corrected PET images are automatically reconstructed in a CT corrected LOR-RAMLA.

2. The CT acquired prior to the PET images is used as the transmission scan and automatically used in the attenuation-corrected PET images.

VI. POST PROCEDURE INSTRUCTIONS

- A. All patients are instructed to maintain safe distance from small children/infants and any persons that are pregnant for 4 hours after the scan.
- B. If a diabetic patient taking metformin received iodinated contrast media, **patient should be instructed to not take their metformin for 2 days** after the scan.
- C. All patients exit the facility immediately following release from the Nuclear Medicine department to avoid unnecessary radiation exposure to others within the facility.

**Attachment B, Need, Item 1
(Project Specific Criteria-PET Service)**

Physician CV's and Certification



**Verification of Certification and Maintenance
of Certification (MOC)**

December 14, 2017

Name: Dr. William Alexander Lankford

Practice Locations: Memphis, TN

Certificate	Status	Valid Through	Maintenance	MOC Requirements
Diagnostic Radiology	Valid	03/02/2046	Not Required	Not Required

The information provided in this letter is considered the primary source verification. The most current certificate and MOC public reporting status information can be accessed at any time for Dr. William Alexander Lankford by entering the required information in the 'Verify board certification status' search on the ABR website at www.theabr.org.

For questions regarding the ABR MOC Program or its participation requirements, please contact the board office at (520) 519-2152 or information@theabr.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Valerie Jackson".

Valerie Jackson, MD
Executive Director
American Board of Radiology

CURRICULUM VITAE

NAME: William A. Lankford, M.D.

ADDRESS: 8800 Poplar
Germantown, TN 38138

DATE OF BIRTH: July 1, 1946

PLACE OF BIRTH: Sikeston, Missouri

EDUCATION: Murray State University, BA degree, 1968

University of Tennessee Medical School,
MD Degree, 1972.

POST-DOCTORATE TRAINING: Internship at Baptist Memorial Hospital,
Memphis, TN, 1972 - 1973.

Radiology Residency at Baptist Memorial
Hospital, Memphis, TN, 1973 - 1976.

LICENSURE AND CERTIFICATION: Medical License issued in June, 1972.

Board Certification in Radiology in June, 1976.

PROFESSIONAL POSITION: Member of the Medical Staff of Baptist
Memorial Hospital from 1976 - 1989.

West Cancer Center
7945 Wolf River Blvd.
Germantown, TN 38138
June 1989 - Present

AFFILIATIONS: Mid-South Clinical Research Institute
6409 Quail Hollow Road, Memphis, TN





**Verification of Certification and Maintenance
of Certification (MOC)**

October 30, 2017

Name: Dr. Scott Leslie Baum
Practice Locations: Memphis, TN
Participating in MOC

Certificate	Status	Valid Through	Maintenance	MOC Requirements
Interventional Radiology/Diagnostic Radiology	Valid	03/02/2019*	Maintained	Meeting

The information provided in this letter is considered the primary source verification. The most current certificate and MOC public reporting status information can be accessed at any time for Dr. Scott Leslie Baum by entering the required information in the 'Verify board certification status' search on the ABR website at www.theabr.org.

For questions regarding the ABR MOC Program or its participation requirements, please contact the board office at (520) 519-2152 or information@theabr.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Valerie Jackson", written over a light blue horizontal line.

Valerie Jackson, MD
Executive Director
American Board of Radiology

*Validity of certification is contingent upon participation in Maintenance of Certification. The ABR recommends verification of certification be repeated annually, three business days after the ABR's March 2nd annual review.

**CURRICULUM VITAE
SCOTT L. BAUM, M.D.**

D.O.B.: November 21, 1957
PLACE OF BIRTH: Atlanta, Georgia
Address: 708 W. Suggs
Memphis, Tennessee 38120

EDUCATION:

College: University of Tennessee, Knoxville, TN
9/75-3/79, BA
Medical College: University of Tennessee, Memphis
8/79-6/83, MD
Internship: St. Louis University, St. Louis, MO
7/83-6/84
Residency: Diagnostic Radiology
St. Louis University, St. Louis, MO
7/84-6/87
Chief Resident: 1986-1987
Fellowship: University of Tennessee, Memphis, TN
Angiography/Interventional Radiology
7/87-6/88

APPOINTMENTS:

PRESENT: West Cancer Center
7945 Wolf River Blvd.
Germantown, TN 38138-1733
10/98-present

NCCN Lung Cancer Screening Panel
Advisory Board Member
2012-present

University of Tennessee Health Science Center
Affiliated Assistant Professor of Radiology Fellowship Program
3/14-present

University of Tennessee Health Science Center
Clinical Assistant Professor of Radiology
7/02-present

Mid-South Imaging and Therapeutics
Co-Director of Angiography/Interventional Radiology Section
7/90-10/98

 12.21.15

Revised 12/21/2015

Clinical Assistant Professor of Radiology
University of Tennessee, Memphis
1990-98

Assistant Professor of Radiology
University of Tennessee, Memphis
1989-90

Instructor of Radiology
University of Tennessee, Memphis, TN
1988-89

BOARD CERTIFICATIONS: American Board of Radiology
June, 1987

SOCIETY MEMBERSHIPS: American College of Radiology
Radiological Society of North America
Society of Cardiovascular and Interventional Radiology
Tennessee Radiological Society

PRESENTATIONS:

1. Percutaneous Management of Peripancreatic Pseudoaneurysms and Collections.
University of Tennessee Surgical Grand Rounds, 1988.
2. Magnetic Resonance Imaging and Oncology
Baptist Memorial Hospital Cancer Symposium, 1988
3. Radiological Evaluation of Cervical Spine Trauma
University of Tennessee Trauma Symposium, 5/88
4. Embolization of Peripheral Pseudoaneurysms
Neuro and Peripheral Interventional Radiology Course
Bermuda, 8/92
Baptist Memorial Hospital Continuing Medical Education Department
5. Embolization with the Mechanical, Detachable Coil
Society of Cardiovascular and Interventional Radiology Annual Meeting
New Orleans, LA 2/93

PUBLICATIONS:

1. Brief Report. Arteriovenous Fistula after Biopsy of Renal Transplant: Diagnosis and Therapy. Pediatric Nephrology, 11:92.
2. Silent Deep Venous Thrombosis in Immobilized Trauma Patients, American Journal of Surgery 158:515-519; 12:89.
3. Bronchial arteriography and Embolotherapy for Hemoptysis in Patients with Cystic Fibrosis. Cardiovascular and Interventional Radiology, 14:241-246, 91.
4. AAST Organ Injury Scale: Correlation of CT-Grade Liver Injury and Operative Findings. Journal of Trauma, 31:806-812, 91.

5. Initial Experience with a Universal Length Co-Polimar Ureteral Stent. Cardiovascular and Interventional Radiology. 90.
6. Trauma Center Imaging Problems: Proposed Solution with Picture Archiving Communication Systems. Journal of Digital Imaging, Vol. 4:79-86, 91.
7. Lung Cancer Screening, Version 1. 2015: Featured Updates to NCCN Guidelines 13:23-34, 15.



Verification of Certification and Maintenance of Certification (MOC)

December 14, 2017

Name: Dr. Daniel Knight Powell
Practice Locations: Memphis, TN
Participating in MOC

Certificate	Status	Valid Through	Maintenance	MOC Requirements
Interventional Radiology/Diagnostic Radiology	Valid	03/02/2019*	Maintained	Meeting

The information provided in this letter is considered the primary source verification. The most current certificate and MOC public reporting status information can be accessed at any time for Dr. Daniel Knight Powell by entering the required information in the 'Verify board certification status' search on the ABR website at www.theabr.org.

For questions regarding the ABR MOC Program or its participation requirements, please contact the board office at (520) 519-2152 or information@theabr.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Valerie Jackson", is written over a faint, light blue circular watermark.

Valerie Jackson, MD
Executive Director
American Board of Radiology

*Validity of certification is contingent upon participation in Maintenance of Certification. The ABR recommends verification of certification be repeated annually, three business days after the ABR's March 2nd annual review.

Daniel K. Powell, MD

danielkpowell@gmail.com
(917) 617-7675

Work and Appointments

Interventional Radiology/Diagnostic Radiology, **West Cancer Center**, Memphis, TN

07/2015 – current

- Oncologic and general radiology, including US; PET/CT; cardiac CT; abdominal, neuro- and MSK MRI
- Interventional oncology, including chemoembolization and radioembolization; biopsies, including breast; venous access; GI and GU interventions.

Post-Graduate Training

Interventional Radiology Fellowship, **New York Presbyterian-Columbia**, New York, NY

07/2014 – 06/2015

Radiology Residency, **Mount Sinai Beth Israel**, New York, NY

07/2010 – 06/2014

Transitional Internship, **Flushing Hospital Medical Center**, Flushing, NY

07/2009 – 06/2010

Education

MD, **Jefferson Medical College**, Philadelphia, PA

09/2005 – 05/2009

Premedical Post-baccalaureate, **Bryn Mawr College**, Bryn Mawr, PA

09/2004 – 06/2005

BA, Literature, **Yale University**, New Haven, CT

08/1998 – 05/2002

Bronx High-School of Science, Bronx, NY

09/1993 – 06/1997

Academic Activities & Grants

Grants and Ongoing research

- Grant recipient principle investigator, Associate Trustees Mt. Sinai St. Luke's and Mt. Sinai Roosevelt Small Grant Award 2014
- FDA Investigational Device Exemption (IDE) approval holder 2014-2015
- Developing an Investigational New Drug (IND) application for the FDA 2014-2015

Peer review

- Reviewer, Radiology 2014-2015
- Reviewer, Journal of Vascular and Interventional Radiology 2013-2015
- Reviewer, Journal of Academic Radiology 2013-2015
- Reviewer, Clinical Radiology 2013-2015



Daniel K. Powell, MD 12/17/2015

- Reviewer, Journal of Clinical Imaging 2012-2015
- Reviewer, American Journal of Neuroradiology 2012-2014
- Reviewer, RSNA physics modules 2013

Leadership and service

- Resident Manager, Angio Simulator Lab, Mount Sinai Beth Israel 2013-2014
- Radiation Safety Committee, Mount Sinai Beth Israel 2012-2013
- Curriculum co-writer, interventional radiology simulator, Mount Sinai Beth Israel 2013
- Created an online research approval and design information repository with guide lines and templates, Mount Sinai Beth Israel 2013
- Proposed a multi-disciplinary information technology research work group to Facilitate approved research 2013

Teaching and interdisciplinary conference

- Interdisciplinary tumor boards (e.g. GI, GU, Gyn, Chest, etc...), attending 2015
- Interesting case conference and morbidity and mortality presentations, fellow 2014-2015
- Regular didactic lectures, journal club presentations and radiologic-pathologic correlation lectures for residents, resident and fellow
- Regular presentations at interdisciplinary meetings, including hepatobiliary, urology, gynecology, head & neck, gastrointestinal and oncology, resident 2011-2015
- Ran regular interventional radiology simulator training sessions, lectures and individual training for each resident, resident 2013-2014
- Periodic radiology lectures for emergency medicine residents, resident 2010-2011

Peer-Reviewed Publications

1. Silberzweig JE, **Powell DK**, Matsumoto AH, Spies JB. State-of-the Art: Management of Uterine Fibroids. *In press Radiology*, 2015.
2. Hao F, **Powell DK**, Sheynzon V. Pediatric Gastroduodenal Embolization with a Microvascular Plug. *Accepted, Cardiovasc Intervent Radiol*, 2015.
3. **Powell DK**, Jamison DK, Silberzweig JE. Introduction of an endovascular simulation basic skills exercise among radiology residents: comparison of simulation test performance with and without practice from a prior case simulation. **Clin Imaging**. 2015 Nov-Dec;39(6):1080-5.
(<http://www.ncbi.nlm.nih.gov/pubmed/26385172>)
4. Whang J, Kolber M, **Powell DK**, Libfeld E. Diffusion-weighted signal patterns of intracranial haemorrhage. **Clin Radiol**. 2015 Aug;70(8):909-16.
(<http://www.ncbi.nlm.nih.gov/pubmed/26050534>)

5. Iyer A, **Powell DK**, Irish R, Math K. Pectus excavatum with delayed diagnosis of implant tear causing recurrent postoperative seromas: a case report. **Skeletal Radiol.** 2015 Aug;44(8):1153-6.
(<http://www.ncbi.nlm.nih.gov/pubmed/25452151>)
6. **Powell DK**, Silberzweig JE. The use of ACR appropriateness criteria: a survey of radiology residents and program directors. **Clin Imaging.** 2015 Mar-Apr;39(2):334-8.
(<http://www.ncbi.nlm.nih.gov/pubmed/25457568>)
7. **Powell DK**, Silberzweig JE. State of structured reporting in radiology, a survey. **Acad Radiol.** 2015 Feb;22(2):226-33.
(<http://www.ncbi.nlm.nih.gov/pubmed/25442793>)
8. **Powell DK**, Shams J. A painful swollen leg. Society of Interventional Radiology Resident and Fellows Section, Case of the Month. December 2014.
(<http://rfs.sirweb.org/wordpressnsta/2014/12/15/case-of-the-month-december-2014-2-of-2/>)
9. **Powell DK**. Patient explanation guidelines to elucidate incidentilomas: helping patients not to fear the delayed surveillance. **AJR Am J Roentgenol.** 2014 Jun; 202(6):W602.
(Letter to the editor)
(<http://www.ncbi.nlm.nih.gov/pubmed/24848860>)
10. Lin E, **Powell DK**, Kagetsu N. Efficacy of a checklist-style structured radiology reporting template in reducing resident misses on cervical spine computed tomography examinations. **J Digit Imaging.** 2014 Oct;27(5):588-93.
(<http://www.ncbi.nlm.nih.gov/pubmed/24865860>)
11. **Powell DK**, Lin E, Silberzweig JE, Kagetsu N. Introducing radiology report checklists among residents: adherence rates when suggesting versus requiring their use and early experience in improving accuracy. **J Acad Rad.** 2014 Mar; 21(3):415-423.
(<http://www.ncbi.nlm.nih.gov/pubmed/24507429>)
12. **Powell DK**, Levin G, Kods K, Yim A, Nicholson D, Kagen A. Comparison of comfort and image quality with two endorectal coils in MRI of the prostate. **J Magn Reson Imaging.** 2014 Feb; 39(2):419-26.
(<http://www.ncbi.nlm.nih.gov/pubmed/23682041>)
13. **Powell DK**, Jacobson AS, Kuflik PL, Persky MS, Silberzweig JE, Khorsandi AS. Fibular flap reconstruction of the cervical spine for repair of osteoradionecrosis. **Spine J.** 2013 Nov; 13(11):e17-21.
(<http://www.ncbi.nlm.nih.gov/pubmed/23932779>)
14. Lynskey GE, **Powell DK**, Dixon RG, Silberzweig JE. Radiation protection in Interventional Radiology: Survey results of attitudes and utilization. **J Vasc Interv Radiol.** 2013 Oct; 24(10):1547-51.e3.

- (<http://www.ncbi.nlm.nih.gov/pubmed/23876553>)
15. **Powell DK**, Goldfarb R, Ongseng F. Hepatobiliary Rim Sign: new implications for acute and complicated cholecystitis. **Nucl Med Commun.** 2013 May; 34(5):467-477.
(<http://www.ncbi.nlm.nih.gov/pubmed/23470462>)
 16. **Powell DK**, Nwoke F, Urken ML, Buchbinder D, Jacobson AS, Silberzweig JE, Khorsandi AS. Scapular free flap harvest site: Recognizing the spectrum of radiographic post-operative appearance. **Br J Radiol.** 2013 Mar; 86(1023):20120574.
(<http://www.ncbi.nlm.nih.gov/pubmed/23392191>)
 17. **Powell DK**, Holliday RA, Chung M, Silberzweig JE. Initial attempts to modify dictation practice. **J Am Coll Radiol.** 2013 Apr; 10(4):296-300.
(<http://www.ncbi.nlm.nih.gov/pubmed/23416034>)
 18. **Powell DK**, Goldfarb R, Nwoke F, Ongseng F. Tc-99m-sestamibi parathyroid gland scintigraphy: added value of Tc-99m-pertechnetate thyroid imaging. **Clin Imaging.** 2013 May-Jun; 37(3):475-9.
(<http://www.ncbi.nlm.nih.gov/pubmed/23102932>)
 19. Murray RC, **Powell D**, Curry JM, Sperling MR, Evans JJ, Spiegel JR. Epileptic Laryngospasm Presenting as a Primary Sleep Disturbance. **Arch Otolaryngol Head Neck Surg.** 2010 Oct; 136(10):1025-7.
(<http://www.ncbi.nlm.nih.gov/pubmed/20956752>)

Textbooks/chapters

1. **Powell DK**, Killam J, Legasto A. Cardiac MRI: ischemic and non-ischemic cardiomyopathy. Saarbrücken, Germany: Lambert Academic Publishing; 2013.
(<http://www.amazon.com/Cardiac-MRI-Ischemic-non-ischemic-cardiomyopathy/dp/3659325864>)
2. **Powell DK**, Seliger G. A common pattern of disease: obstructive and non-obstructive dilated small bowel. Saarbrücken, Germany: Lambert Academic Publishing; 2012.
(<http://www.amazon.com/Common-pattern-disease-Obstructive-non-obstructive/dp/3659147958>)

Awards & Honors

- Outstanding Reviewer – Clinical Imaging 2015
- Who's Who in America, 70th edition 2016
- 2014 Top Reviewer for the Journal of Vascular and Interventional Radiology 2014
- Recognition for Dedication to Improving Quality and Patient Safety Initiatives, Mount Sinai Beth Israel 2014

- ACR/RRA/RAHSR/ AUR Scholar Program
 - Also sub-selected for Oral Scholar Presentation
- 2013 Top Reviewer for the Journal of Vascular and Interventional Radiology 2013
- Second place (Academic papers), Beth Israel Medical Center Essay Contest 2013
- Invitation to the Gastrointestinal *Power Hour*, ARRS Annual meeting 2013
- Honorable Mention Semi-finalist: Beth Israel Medical Center Research Fair 2013
- Roentgen Resident Research Award 2012
- Introduction to Academic Radiology Program, ARRS 2012
- CME Discussion, RSNA Annual Meeting 2012
- Honorable Mention Semi-finalist: Beth Israel Medical Center Research Fair 2012
- Invitation to the Nuclear Medicine *Power Hour*, ARRS Annual meeting 2011
- Basic Cancer Research Grant, Thomas Jefferson University 2006
- Basic Cancer Research Grant, Thomas Jefferson University 2005
- Project Health Care Internship, Bellevue Hospital 2000
- Semi-finalist, Westinghouse Science Talent Search 1997

National Meeting Presentations

1. **Powell DK, Jamison DK, Silberzweig JE.** Introduction of an endovascular simulation curriculum among radiology residents. Scientific program poster presentation, SIR Annual Scientific Meeting, February-March, 2015.
2. **Powell DK, Silberzweig JE.** Simulator machine endovascular curriculum: the introduction of a program among radiology trainees and initial results. AUR Scholar Program Oral Presentation, AUR Annual Meeting, April, 2014.
3. **Powell DK, Levin G, Kodsi K, Yim A, Kagen A.** Endorectal Coil Selection in Prostate MRI: focus on patient comfort and image quality. Scientific exhibit, ARRS Annual Meeting, April 2013.
4. **Powell DK, Holliday RA, Chung M, Szilagyi S, Silberzweig JE.** Universal reporting language: elimination of inappropriate terms. Scientific Informal Presentation, RSNA Annual Meeting, November 2012.
5. **Powell DK, Silberzweig JE, Lin E, Merunka V, Kagetsu N.** Checklist may be safe, but they don't teach: Introducing checklist structured reporting to residents. Scientific Informal Presentation, RSNA Annual Meeting, November 2012.
6. **Powell DK, Vairavamurthy J, Killam J, Legasto A.** Cardiac No-Reflow Phenomenon. Computer Education Exhibit Presentation, RSNA Annual Meeting, November 2012.
7. **Powell D, Morales E, Seliger G.** Dilated obstructive and non-obstructive Small Bowel Disease. Electronic Presentation, ARRS Annual Meeting, May 2012.

8. **Powell D**, Libfeld E. Diagnosis of early spinal cord infarction with diffusion weighted imaging (DWI). Excerpta extraordinaria (scientific exhibit), American Society of Spine Radiology Symposium, February 2012.
9. **Powell D**, Goldfarb R, Ongseng F. Pericholecystic Hepatic Uptake on Hepatoscintigraphy and its Implications for Complicated and Non-complicated Acute Cholecystitis. Electronic Presentation, ARRS Annual Meeting, May 2011.
10. **Powell DK**, Antoci V Jr., Jose B, Parvizi J, Zeiges AR, Shapiro IM, Wickstrom E, Adams CS, Hickok NJ. Delivery of Doxorubicin By Titanium Implants. Poster presentation, Orthopaedic Research Society Annual Meeting, 2006.
11. **Powell D**, Nash C. Adolescent Responses to Authority. Westinghouse Science Talent Search, 1997.

Abstracts

1. Lin E, **Powell D**, Kagetsu NJ. Efficacy of Checklist-Style Structured Reporting In Reducing Missed Findings In Resident Preliminary Reports. American Society of Neuroradiology Annual Meeting, 2012.
2. Antoci V Jr, Adams CS, **Powell DK**, Antoci V, Hickok N, Shapire IM, Parvizi J. High Dose, Common Antibiotics Inhibit Cellular Proliferation. Proceedings of the Orthopaedic Research Society, 2006.
3. Antoci V Jr., Adams CS, **Powell DK**, Antoci V, Hickok NJ, Shapiro IM, Parvizi J. Where is the Balance for Antibiotic Concentration in Methylmethacrylate Cement? International Society for Technology in Arthroplasty, 2006.
4. Antoci V Jr., Adams CS, **Powell DK**, Antoci V, Hickok NJ, Shapiro IM, Parvizi J. Cytotoxicity as a Function of Antibiotic Concentration Released from Cement. Proceedings of the Musculoskeletal Infection Society, 2006.
5. Antoci V Jr., Adams CS, **Powell DK**, Antoci V, Hickok NJ, Shapiro IM, Parvizi J. High Dose Common Antibiotics Inhibit Cellular Proliferation. Proceedings of the Orthopaedic Research Society, 2006

Local Meeting Presentations

1. **Powell DK**, Levin G, Kods K, Yim A, Kagen A. Endorectal Coil Selection in Prostate MRI: focus on patient comfort and image quality. Beth Israel Medical Center Research Fair 2013. *Honorable Mention Semi-finalist.*
2. **Powell DK**, Nwoke F, Urken ML, Buchbinder D, Jacobson AS, Silberzweig JE, Khorsandi AS. Scapular free flap harvest site: Recognizing the spectrum of radiographic post-operative appearance. Beth Israel Medical Center Research Fair 2013.

3. **Powell DK**, Morales E, Seliger G. Dilated obstructive and non-obstructive small bowel disease. Beth Israel Medical Center Research Fair 2012. *Honorable Mention Semi-finalist*.
4. **Powell DK**, Goldfarb RC, Ongseng F. Hepatobiliary Rim Sign: New Implications for Acute and Complicated Cholecystitis. Beth Israel Medical Center Research Fair 2012.
5. **Powell D**, Vaivaramurthy J, Legasto A. Cardiac No-Reflow Phenomenon. Beth Israel Medical Center Research Fair, 2012.
6. **Powell D**, Libfeld E. Diagnosis of presumed early spinal cord infarction with diffusion weighted imaging (DWI). Beth Israel Medical Center Research Fair, 2012.
7. **Powell DK**, Lin E, Merunka V, Silberzweig J, Kagetsu N. Checklists May Be Safe, But They Don't Teach: Introducing Structured Reporting to Residents. Beth Israel Medical Center Research Fair, 2012.
8. **Powell DK**, Soto E, Do Ouro S, Lidov M, It's Rare, But Beware If It's In There: Intrathecal catheter tip granuloma/inflammatory mass. Beth Israel Medical Center Research Fair, 2012.
9. **Powell DK**, Antoci V Jr., Jose B, Parvizi J, Zeiges AR, Shapiro IM, Wickstrom E, Adams CS, Hickok NJ. Site-Directed Chemotherapy Delivery: Doxorubicin-Modified Titanium. Sigma Xi Research Day, Thomas Jefferson University, 2006.

Work During Medical School

Thomas Jefferson University - Orthopedic Research laboratory	09/2006 – 07/2009
Laboratory assistant	
-Synthesis of chemotherapeutic and antibiotic surfaces, testing their effects on osteoblasts, osteosarcoma and <i>s. aureas</i>	
Basic science cancer research intern, grant recipient	06/2006 – 08/2006
Children's Hospital of Philadelphia and St Christopher's Hospital	10/2006 – 06/2007
Certified Spanish Interpreter - (Phoenix Language Services and Lingual Institute)	
-Trained 100 hours in professional interpreting in the classroom, simulation, and under observation	
-Worked as an interpreter for office visits, inpatients and procedures	
JeffHOPE	06/2005 – 6/2007
Homeless shelter clinic	
Primary care "office" visits under preceptor supervision	
District Health Care Center #3	10/2004 – 6/2005
French and Spanish interpretation for clinic visits	
Assisted in playroom and pre-natal clinic	

Employment/Occupation between schooling ("gaps in training")Between College and Medical School

Orthopedic Research Laboratory, Jefferson Medical College	06/2005 – 08/2005
Basic science cancer research intern, grant recipient	
Bryn Mawr College, Bryn Mawr, PA	09/2004 – 06/2005
Pre-medical Post-baccalaureate certification	
Hospital Sant Joan de Deu (Pediatric Hospital), Barcelona, Spain	05/2004 – 08/2004
Volunteer	
Cours de Langue et Civilisation Francaise (French language course)	02/2004 – 04/2004
L'Universite Paris-Sorbonne	
Government Office of Pharmaceutical Publicity (Madrid, Spain)	12/2003 - 02/2004
Translator and office assistant	
Corkery Group	01/2003 – 12/2003
Healthcare public relations and strategy consultant.	
Public Policy Productions	07/2002 – 12/2002
Documentary Production Assistant "Waging a Living" and "Aging Out"	

Between High School and College (deferred admissions of on-schedule acceptance)

3D Construction	07/1997 – 11/1997
Laborer	
Alotepec High School 52, Mexico	12/1997 – 05/1998
English Teacher, high school and grade school	
Morgan Stanley-Dean Witter	06/1998 – 08/1998
Information Technology administrative assistant and web developer	

**Attachment B, Need, Item E
(Service Area Utilization)**

Revised Page 30

Demographic Characteristics of Service Area by County

Supplemental #1

August 29, 2018

9:33 A.M.

Demographic	Shelby County	Tennessee
Age 65+ Population – 2018	125,618	1,119,024
% of Total Population	13.3%	16.5%
Age 65+ Population – 2020	133,579	1,189,428
% of Total Population	14.1%	17.3%
TennCare Enrollees (4/18)	245,409	1,432,475
Percent of 2018 Population Enrolled in TennCare	26%	21.2%
Persons Below Poverty Level (2018)	196,471	1,100,169
Persons Below Poverty Level as % of Population (US Census)	21.4%	17.2%

- E. Describe the existing and approved but unimplemented services of similar healthcare providers in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. List each provider and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: Admissions or discharges, patient days, average length of stay, and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc. This doesn't apply to projects that are solely relocating a service.

Response: Please see table below for utilization for Shelby County linear accelerators and PET scanners.

**Shelby County
Linear Accelerators
Utilization**

Shelby County Providers	Number of Scanners	Treatments		
		2014	2015	2016
West Cancer Center	3/2		11,009	18,204
Baptist Memorial Hospital-Memphis	2	10,590	9,968	9,064
Baptist Memorial Hospital Tipton-Bartlett	1	4,647	4,694	3,782
Methodist Healthcare-University Hospital	2/3	24,739	13,896	13,810
St. Francis Hospital	2	6,332	5,985	4,538
TOTAL	11/9	50,832	45,552	49,398
AVERAGE NUMBER/YEAR		6,354	5,061	5,489

Note: St. Jude Children's Research Hospital has been excluded because it only serves children; this project only serves adults.

Source: HSDA, Equipment Registry, Linear Accelerators - Utilization (As of 7/17/2017). Utilization for St. Francis Hospital is taken from the Joint Annual Report for Hospitals, 2016; It appears what was reported on the equipment registry was a typo.

Attachment B, Economic Feasibility, Item B

Bank Letter



Supplemental #1

August 29, 2018

9:33 A.M.

August 28, 2018

Via Email

Ron Davis
Chief Financial Officer
The West Cancer Center
7945 Wolf River Blvd
Germantown, TN 38138

Re: Preliminary indication of interest in providing financing for a PET and Linear Accelerators Project

Dear Ron,

I am writing to confirm SunTrust Bank's favorable conversations with Ron Davis, CFO with The West Cancer Center, regarding the acquisition of PET and Linear Accelerators equipment with physician ownership in Germantown, Tennessee (the "Project") and to express SunTrust Bank's initial interest in providing financing for the Project. As discussed, we currently anticipate that we would offer financing in an approximate aggregate principal amount of \$ 12.5 million to the Project (the "Loan"). The anticipated terms of the Loan are currently expected to include a 96 month term and a fixed rate of interest of approximately 5.35%. The anticipated terms of the Loan are preliminary and subject to change, and do not reflect all of the material terms of the Loan which may be required as part of SunTrust Bank's underwriting requirements, which terms may include, without limitation, the grant of a security interest in some or all of the assets of the Project, certain affirmative and negative covenants, and other standard terms and conditions. SunTrust Bank's willingness to extend the Loan is further subject in its entirety to normal underwriting review and all necessary approvals.

Sincerely,

A handwritten signature in black ink, appearing to read "Jim Hopkins", with a stylized flourish extending from the end.

Jim Hopkins
Vice President

SunTrust Medical Specialty Group
999 South Shady Grove Suite 210
Memphis, TN 38120
P: 901-415-7324
F: 901-684-6281

**Attachment B, Economic Feasibility, Item D, Projected Data
Charts**

Revised Pages 38-41

**PROJECTED DATA CHART
LINEAR ACCELERATORS**

Supplemental #1
August 29, 2018
0:33 AM

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in January (Month).

		Year 2019	Year 2020
A.	Utilization Data (Specify unit of measure, e.g., 1,000 patient days, 500 visits) Unit of Measure = MRT procedures	19,250	19,300
B.	Revenue from Services to Patients		
1.	Inpatient Services Not applicable	\$	\$
2.	Outpatient Services Not applicable	\$	\$
3.	Emergency Services Not applicable		
4.	Other Operating Revenue (Specify) Technical, Medical Physics and Professional Charges	\$84,588,283	\$85,434,166
	Gross Operating Revenue	\$84,588,283	\$85,434,166
C.	Deductions from Gross Operating Revenue		
1.	Contractual Adjustments	-\$63,483,505	-\$64,118,341
2.	Provision for Charity Care	-\$1,670,619	-\$1,687,325
3.	Provisions for Bad Debt	-\$1,670,619	-\$1,687,325
	Total Deductions	-\$66,824,743	-\$67,492,991
	NET OPERATING REVENUE	\$17,763,539	\$17,941,175
D.	Operating Expenses		
1.	Salaries and Wages and Benefits		
a.	Direct Patient Care	\$2,345,646	\$2,416,015
b.	Non-Patient Care	\$260,627	\$268,446
2.	Physician's Salaries and Wages	\$2,997,137	\$3,027,108
3.	Supplies	\$142,959	\$147,248
4.	Rent		
a.	Paid to Affiliates		
b.	Paid to Non-Affiliates		
5.	Management Fees:	\$	\$
a.	Paid to Affiliates		
b.	Paid to Non-Affiliates		
6.	Other Operating Expenses: maintenance contracts, repairs, non-med supplies/exp; overhead allocation exp.	\$4,422,596	\$4,491,833
	Total Operating Expenses	\$10,168,965	\$10,350,650
E.	Earnings Before Interest, Taxes and Depreciation	\$7,594,574	\$7,590,525
F.	Non-Operating Expenses		
1.	Taxes	\$	\$
2.	Depreciation	\$500,000	\$500,000
3.	Interest	\$234,689	\$222,988
4.	Other Non-Operating Expenses		
	Total Non-Operating Expenses	\$734,689	\$722,988
	NET INCOME (LOSS)	\$6,859,885	\$6,867,537

Chart Continues Onto Next Page

Supplemental #1**August 29, 2018** \$6,867,537**9:33 A.M.****NET INCOME (LOSS)****G. Other Deductions**

1. Estimated Annual Principal Debt Repayment
2. Annual Capital Expenditure

Total Other Deductions**NET BALANCE****DEPRECIATION****FREE CASH FLOW (Net Balance + Depreciation)**

\$230,305	\$233,760
	\$
\$230,305	\$233,760
\$6,629,580	\$6,633,777
\$500,000	\$500,000
\$7,129,580	\$7,133,777

- ☐ Total Facility
☒ Project Only

PROJECTED DATA CHART-OTHER EXPENSES**OTHER EXPENSES CATEGORIES**

1. Maintenance Contracts
 2. Repairs
 3. Non-medical Supplies and Expenses
 4. Overhead Allocation Expenses
- Total Other Expenses**

Year 2019	Year 2020
\$800,670	\$800,670
\$100,594	\$101,600
\$349,271	\$385,782
\$3,172,061	\$3,203,781
\$4,422,596	\$4,491,833

**PROJECTED DATA CHART
PET/CT**

Supplemental #1

August 29, 2018

9:33 A.M. ☐ Total Facility

☒ Project Only

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in January (Month).

	Year 2019	Year 2020
A. Utilization Data (Specify unit of measure, e.g., 1,000 patient days, 500 visits) Unit of Measure = PET/CT procedures	1,800	1,820
B. Revenue from Services to Patients		
1. Inpatient Services Not applicable		
2. Outpatient Services Not applicable		
3. Emergency Services Not applicable		
4. Other Operating Revenue (Specify) Technical, Medical Physics and Professional Charges	\$23,315,650	\$23,548,807
Gross Operating Revenue	\$23,315,650	\$23,548,807
C. Deductions from Gross Operating Revenue		
1. Contractual Adjustments	-\$18,605,888	-\$18,791,947
2. Provision for Charity Care	-\$489,629	-\$494,525
3. Provisions for Bad Debt	-\$489,629	-\$494,525
Total Deductions	-\$19,585,146	-\$19,780,997
NET OPERATING REVENUE	\$3,730,504	\$3,767,810
D. Operating Expenses		
1. Salaries and Wages and Benefits		
a. Direct Patient Care	\$243,691	\$251,002
b. Non-Patient Care		
2. Physician's Salaries and Wages	\$530,250	\$535,553
3. Supplies	\$352,699	\$363,280
4. Rent		
a. Paid to Affiliates		
b. Paid to Non-Affiliates		
5. Management Fees:	\$	\$
a. Paid to Affiliates		
b. Paid to Non-Affiliates		
6. Other Operating Expenses: Maintenance contracts; repairs; non-medical supplies/exp., overhead allocation expenses	\$1,068,197	\$1,082,756
Total Operating Expenses	\$2,194,837	\$2,232,590
E. Earnings Before Interest, Taxes and Depreciation	\$1,535,667	\$1,535,219
F. Non-Operating Expenses		
1. Taxes	\$	\$
2. Depreciation	\$40,000	\$40,000
3. Interest	\$62,186	\$59,086
4. Other Non-Operating Expenses		
Total Non-Operating Expenses	\$102,186	\$99,086
NET INCOME (LOSS)	\$1,433,481	\$1,436,133

Chart Continues Onto Next Page

NET INCOME (LOSS)	<u>\$1,433,481</u>	<u>\$1,436,133</u>
G. Other Deductions		
1. Estimated Annual Principal Debt Repayment	<u>\$61,025</u>	<u>\$61,940</u>
2. Annual Capital Expenditure		<u>\$</u>
Total Other Deductions	<u>\$61,025</u>	<u>\$61,940</u>
NET BALANCE	<u>\$1,372,456</u>	<u>\$1,374,193</u>
DEPRECIATION	<u>\$40,000</u>	<u>\$40,000</u>
FREE CASH FLOW (Net Balance + Depreciation)	<u>1,412,456</u>	<u>\$1,414,193</u>

☐ Total Facility

☒ Project Only

PROJECTED DATA CHART-OTHER EXPENSES

<u>OTHER EXPENSES CATEGORIES</u>	<u>Year 2019</u>	<u>Year 2020</u>
1. Maintenance Contracts	<u>\$157,350</u>	<u>\$157,350</u>
2. Repairs	<u>\$5,000</u>	<u>\$5,000</u>
3. Non-Medical Supplies and Expenses	<u>\$31,510</u>	<u>\$37,326</u>
4. Overhead Allocation Expenses	<u>\$874,337</u>	<u>\$883,080</u>
Total Other Expenses	<u>\$1,068,197</u>	<u>\$1,082,756</u>

Attachment B, Economic Feasibility, Item F.1

**Balance Sheet
Income Statement**

The West Clinic, PC
Balance Sheet
For The Period Ending July 31, 2018

	<u>2018</u>
ASSETS	
Current Assets	
Cash	\$ 7,960,266
Non-patient Accounts Receivable	2,404,037
Total Current Assets	<u>10,364,303</u>
Fixed Assets	
Property, Plant and Equipment	473,509
Accumulated Depreciation	<u>(460,391)</u>
Total Fixed Assets	13,117
Other Assets	
Due From/To Methodist	-
Net Intangible Assets - Vector Contracts	73,895
TOTAL ASSETS	<u><u>10,451,315</u></u>
 LIABILITIES AND STOCKHOLDERS' DEFICIT	
Current Liabilities	
Payable	\$ 1,310,276
Payroll Withholdings	186,883
Due From/To Methodist	7,077,011
Unapplied Cash	<u>33,246</u>
	8,607,417
Long-Term Debt	
Notes Payable	1,000,000
Other	<u>236,682</u>
	1,236,682
Stockholders' Deficit	
Common Stock	1,000
Treasury Stock	(362,585)
Additional Paid-In Capital	1,048
Retained Earnings	<u>967,753</u>
	607,217
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	<u><u>10,451,315</u></u>

The West Clinic, PC
Income Statement
For Seven Months Ending July 31, 2018

	<u>2018</u>
REVENUE	
Total Revenue	\$ 46,382,659
Cost of Sales	<u>(15,326,500)</u>
Gross Profit	31,056,159
EXPENSES	
Operating & Physician Expenses	26,875,881
Net Operating Income	<u>4,180,278</u>
OTHER EXPENSES	
Depreciation	4,684
Interest Expense	<u>57,537</u>
Total Other Expenses	62,221
Net Income	<u><u>4,118,057</u></u>

Attachment B, Economic Feasibility, Item F.3

Revised Page 43

3. project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

Response:

- F. 1) Discuss how projected utilization rates will be sufficient to support the financial performance. Indicate when the project's financial breakeven is expected and demonstrate the availability of sufficient cash flow until financial viability is achieved. Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For all projects, provide financial information for the corporation, partnership, or principal parties that will be a source of funding for the project. Copies must be inserted at the end of the application, in the correct alpha-numeric order and labeled as Attachment C, Economic Feasibility. **NOTE: Publicly held entities only need to reference their SEC filings.**

Response: . The volume utilization of both the linear accelerators and the PET/CT are above HSDA volume guidelines. The project will be above breakeven and profitable from its inception.

- 2) Net Operating Margin Ratio – Demonstrates how much revenue is left over after all the variable or operating costs have been paid. The formula for this ratio is: (Earnings before interest, Taxes, and Depreciation/Net Operating Revenue).

Utilizing information from the Historical and Projected Data Charts please report the net operating margin ratio trends in the following table:

Year	2nd Year previous to Current Year	1st Year previous to Current Year	Current Year	Projected Year 1	Projected Year 2
Net Operating Margin Ratio/ LinAcc	N/A	N/A	N/A	42.8	42.3
Net Operating Margin Ratio/ PET/CT	N/A	N/A	N/A	41.2	40.8

- 3) Capitalization Ratio (Long-term debt to capitalization) – Measures the proportion of debt financing in a business's permanent (Long-term) financing mix. This ratio best measures a business's true capital structure because it is not affected by short-term financing decisions. The formula for this ratio is: (Long-term debt/(Long-term debt/Total Equity (Net assets)) x 100).

For the entity (applicant and/or parent company) that is funding the proposed project please provide the capitalization ratio using the most recent year available from the funding entity's audited balance sheet, if applicable. The Capitalization Ratios are not expected from outside the company lenders that provide funding.

Response:

- G. Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid and medically indigent patients will be served by the project. Additionally, report the estimated gross revenue dollar amount and percentage of projected gross operating revenue anticipated by payor classification for the first year of the project by completing the table below.

Attachment B, Economic Feasibility, Item H

Revised Page 46

Germantown PET:

Position Classification	Existing FTEs (enter year)	Projected FTEs Year 1	Average Wage (Contractual Rate)	Area Wide/Statewide Average Wage
A. Direct Patient Care Positions				
<i>Position 1: Nuclear Medicine Tech</i>	3	3	\$65,520	\$65,530
<i>Position 2</i>				
<i>Position 3 -</i>				
Total Direct Patient Care Positions	3	3		

B. Non-Patient Care Positions				
<i>Position 1:</i>	0	0	0	
<i>Position 2:</i>	0	0	0	
<i>Position 3:</i>	0	0	0	
Total Non-Patient Care Positions	0	0	0	
Total Employees (A+B)	3	3		
C. Contractual Staff				
Total Staff (A+B+C)	3	3		

I. Describe all alternatives to this project which were considered and discuss the advantages and disadvantages of each alternative including but not limited to:

- 1) Discuss the availability of less costly, more effective and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, justify why not, including reasons as to why they were rejected.

Response: There are no less costly, more effective and/or more efficient alternative methods of providing the benefits intended by the proposal. These services are already highly utilized by the patients of the West Clinic. It is the applicant's understanding that only one other scanner in the county is a PET/CT, and it is located at Baptist. The benefits of being able to offer PET/CT for cancer patients are numerous, and it is generally considered the standard of care. PET/CT technology integrates the molecular-level diagnostic capabilities of positron emission tomography (PET) with computed tomography (CT) to produce anatomic views, a practice known as image fusion or co-registration. These views allow clinical information from two different exams to be correlated and interpreted on one image, leading to more precise information and accurate diagnoses. PET/CT is prevalent in diagnosing and monitoring progression/regression of cancer.

Attachment B, Need, Orderly Development, Item D

ACR Accreditation



American College of Radiology

PET Services of

West Cancer Center

**7945 Wolf River Blvd.
Germantown, Tennessee 38138**

were surveyed by the
Committee on Nuclear Medicine Accreditation of the
Commission on Quality and Safety

The following unit was approved

Siemens BIOGRAPH 16 2011

For

Oncology

Accredited from:

November 05, 2017 through November 05, 2020

M. Ahesani

CHAIR, COMMITTEE ON NUCLEAR MEDICINE ACCREDITATION

Alan Kaye MD, FAcR

PRESIDENT, AMERICAN COLLEGE OF RADIOLOGY


08/29/2018 09:33

AFFIDAVIT

STATE OF TENNESSEE
COUNTY OF DAVIDSON

NAME OF FACILITY: WEST CANCER CENTER, CN1808-038

I, KIM H. LOONEY, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.



Signature/Title

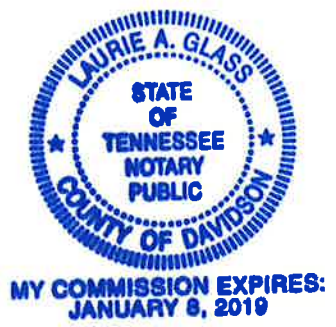
Sworn to and subscribed before me, a Notary Public, this the 29TH day of August, 2018, witness my hand at office in the County of Davidson, State of Tennessee.



NOTARY PUBLIC

My commission expires: January 8, 2019

HF-0043
Revised 7/02



Supplemental #2 (Original)

West Cancer Center
-Germantown

CN1808-038

August 30, 2018

VIA HAND DELIVERY

Phillip Earhart
HSD Examiner
State of Tennessee
Health Services and Development Agency
Andrew Jackson Building
9th Floor
502 Deaderick
Nashville, TN 37243

Re: West Cancer Center - Germantown - CN1808-038
Second Supplemental Responses

Dear Phillip:

This letter is submitted as the supplemental response to your letter dated August 30, 2018, wherein additional information or clarification was requested regarding the above-referenced CON application.

1. Section A, Project Details, Item 6.A

The unwind agreement between Methodist Le Bonheur Healthcare and the West Clinic, PC is noted. However, in the Section labeled "I. Transaction", it appears the applicant's address of 7945 Wolf River Boulevard, Germantown, TN 38138 is not a part of the agreement. Please clarify.

Response: In 2012, when the unwind agreement was executed, The Cancer Center had not moved to its Wolf River location. Although this particular location is not specifically listed, it is clear that it should be included as it is one of the Cancer Center Sites.

2. Section B, Need Item 1 (Project Specific Criteria – PET Service), Item 6.d

It is noted the applicant referenced an attachment that included protocols to assure PET procedures performed will be medically necessary and will not duplicate other services. However, the referenced attachment appeared to not include those protocols. Please provide documentation that assures that all clinical PET procedures performed are medically necessary and will not unnecessarily duplicate other services.

Response: The applicant performs pre-certification or if the payer does not require pre-certification a financial review is performed to ensure that any scans that are

performed are medically necessary and will not duplicate other services. Please see a Radiology Checklist included as Attachment B, Need Item 1 (Project Specific Criteria – PET Service), Item 6.d which describes this process.

3. Section B, Need, Item E (Service Area Utilization)

The Shelby County linear accelerator utilization table on the bottom of page 30R is noted. However, the total number of scanner column appears to be 10/10 rather than 11/9. Please clarify and provide a corrected page 30 (labeled as 30R2) if necessary.

Response: Please see revised page 30-R2 correcting linear accelerator table included as Attachment B, Need, Item E (Service Area Utilization).

If you have any questions please contact me at Kim.Looney@wallerlaw.com or by telephone at 615-850-8722.

Sincerely,



Kim Harvey Looney

KHL:lag
Attachments

**Attachment B, Need, Item 1 (Project Specific Criteria-PET
Service), Item 6.d**

Radiology Checklist

The University of Tennessee

WEST
Cancer Center

Methodist Healthcare Family

RADIOLOGY CHECKLIST

1. Verify Order
 - a. Type of Procedure
 - b. Diagnosis code on the order (ICD-10 on order)
 - c. Start Date - should be DOS
2. QCL comment
 - a. Start Date – should be Order date
 - b. Due Date – should be DOS
 - c. Edit QCL SOP = DOS/Procedure/Insurance (EX: 8/5/16 CT CAP – BCBS TN)
3. Verify patient has been scheduled for “Test Date” Confirmation.
4. Verify if there are any other duplicate QCL’s for that order. If Duplicate – put in comment “DUP” and Skip.
5. Send back to **POD** if any information is missing (ACTION REQUIRED) or if add-on email –send email back to the chain.
6. Approve Xray & Ultrasound for patients after medical necessity review. No Precert is required for these procedures. (for approval - /// approved)
7. Start Precert/medical necessity review & complete. Complete the below steps at least 2 days prior to TEST.
 - a. Medical Necessity Review compares ICD 10 on order to payer poliices to ensure Medical Necessity is met. Review most recent clinical documentation to confirm signs and symptoms support the ICD 10 (Diagnosis) on the order.
 - b. Verify that patient has not had same test recently (according to payer guidelines)
 - c. Pending Precert – send Action Required QCL to POD. If no precert is required – perform a financial/medical necessity review for the procedure. (give case# and if option of expedite)
 - d. Pending P2P – send Action Required QCL to POD (give case# & number)
 - e. Denial – Sent QCL to POD for alternate option
 - i. Send Action Required QCL to Kirby Scheduling for re-schedule per POD response
 - ii. If POD asks to leave test on – send Action Required QCL to Pt reps for ABN or estimate
8. To Enter a AUTH:
 - a. Go to Facesheet
 - b. Double click Insurance then Auths
 - c. Add – Dept: Global, Type: No. of Procedures, Authorization #, Description (CPT CODE), effective date and expiration date, Number approved (change to # of CPT’s).

**Attachment B, Need, Item E
(Service Area Utilization)**

Revised Page 30-R2

Demographic Characteristics of Service Area by County, 2018

August 30, 2018
4:21 P.M.

Demographic	Shelby County	Tennessee
Age 65+ Population – 2018	125,618	1,119,024
% of Total Population	13.3%	16.5%
Age 65+ Population – 2020	133,579	1,189,428
% of Total Population	14.1%	17.3%
TennCare Enrollees (4/18)	245,409	1,432,475
Percent of 2018 Population Enrolled in TennCare	26%	21.2%
Persons Below Poverty Level (2018)	196,471	1,100,169
Persons Below Poverty Level as % of Population (US Census)	21.4%	17.2%

- E. Describe the existing and approved but unimplemented services of similar healthcare providers in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. List each provider and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: Admissions or discharges, patient days, average length of stay, and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc. This doesn't apply to projects that are solely relocating a service.

Response: Please see table below for utilization for Shelby County linear accelerators and PET scanners.

**Shelby County
Linear Accelerators
Utilization**

Shelby County Providers	Number of Scanners	Treatments		
		2014	2015	2016
West Cancer Center	3/2		11,009	18,204
Baptist Memorial Hospital-Memphis	2	10,590	9,968	9,064
Baptist Memorial Hospital Tipton-Bartlett	1	4,647	4,694	3,782
Methodist Healthcare-University Hospital	2/3	24,739	13,896	13,810
St. Francis Hospital	2	6,332	5,985	4,538
TOTAL	10/10	50,832	45,552	49,398
AVERAGE NUMBER/YEAR		6,354	5,061	5,489

Note: St. Jude Children's Research Hospital has been excluded because it only serves children; this project only serves adults.

Source: HSDA, Equipment Registry, Linear Accelerators - Utilization (As of 7/17/2017). Utilization for St. Francis Hospital is taken from the Joint Annual Report for Hospitals, 2016; It appears what was reported on the equipment registry was a typo.

AUG 30 '18 PM 4:21

Supplemental #2

August 30, 2018

4:21 P.M.

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

NAME OF FACILITY: WEST CANCER CENTER, CN1808-038

I, KIM H. LOONEY, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.


Signature/Title

Sworn to and subscribed before me, a Notary Public, this the 30th day of August, 2018, witness my hand at office in the County of Davidson, State of Tennessee.


NOTARY PUBLIC

My commission expires: January 8, 2019

HF-0043

Revised 7/02



**MY COMMISSION EXPIRES:
JANUARY 8, 2019**



**Additional
Information**

**August 29, 2018
2:16 P.M.**

Kim Harvey Looney
615.850.8722 direct
kim.looney@wallerlaw.com

August 29, 2018

VIA HAND DELIVERY

Phillip Earhart
HSDA Examiner
State of Tennessee
Health Services and Development Agency
Andrew Jackson Building
9th Floor
502 Deaderick
Nashville, TN 37243

Re: West Cancer Center-Germantown CN18o8-038

Dear Phillip:

In lieu of executed options for the supplemental responses for West Cancer Center in Germantown, please find an unwind agreement that has been redacted due to its confidential nature. This executed agreement shows that, effective January 1, 2019, Methodist LeBonheur agrees to sell anything necessary for The West Clinic, P.C. to operate the West Cancer Center. This agreement is included in Attachment A, Project Details, Item 6-A, and is included with this letter.

Also included is a cancer incident and mortality rates by site chart, Attachment B, Need, Item 1-8b, that was inadvertently missing from the supplemental responses filed this morning.

Please let me know if you have any questions.

Sincerely,

Kim Harvey Looney

KHL:lag

Attachment A, Project Details, Item 6.A

Redacted Unwind Agreement

UNWIND AGREEMENT

THIS UNWIND AGREEMENT (this "*Agreement*") is made and entered into, as of January 1, 2012 (the "*Effective Date*"), by and between Methodist Le Bonheur Healthcare, a Tennessee nonprofit hospital corporation ("*MLH*"), and West Clinic, PC, a Tennessee professional corporation ("*Practice*"). MLH and Practice are sometimes collectively referred to in this Agreement as the "parties" or, individually, as a "party."

RECITALS

B. All of the agreements listed in the preceding recital (the "*Affiliation Agreements*") are part of an integrated transaction and the parties desire to have a mechanism for an orderly transition and unwind process upon the termination of such agreements.

C. This Agreement describes (i) the process for Practice to acquire all of the assets and assume all of the related liabilities of the Cancer Center Sites (as defined below), which, as of the Effective Date, will be operated as provider-based locations of the MHMH Hospitals (as defined in the Professional Services Agreement), and (ii) the assistance to be provided by MLH in connection with transitioning the Cancer Center Sites to Practice as described below. MLH and Practice desire to undertake the unwind process described in this Agreement in a manner that does not disrupt patient care.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and the mutual agreements hereinafter set forth, the parties hereto agree as follows:

I. TRANSACTION

1.1 Intent of the Parties. The parties intend that, upon an Unwind Event (as defined below), Practice will re-establish a private practice of medicine at any or all of the following locations: 100 Humphreys Blvd., Memphis, Tennessee, 1588 Union Avenue, Memphis Tennessee, 7668 South Airways Blvd., Southaven, Mississippi, 1500 West Poplar Avenue, Suite #304, Collierville, Tennessee and 240 Grandview Drive, Brighton, Tennessee (collectively, the "*Cancer Center Sites*").

1.2 Unwind Events. Except as otherwise provided herein, each of the following shall each be considered an "Unwind Event" and, together, shall be considered "Unwind Events": (i)

1.3 Obligations and Rights upon Unwind Events. Unless otherwise agreed to by the parties, if an Unwind Event results in termination of the Affiliation Agreements, (i) Practice shall acquire all of the assets and assume all of the related liabilities of the Cancer Center Sites, (ii)

r

1.3.1 As of the Unwind Date, Practice shall purchase or repurchase from MLH or its affiliate(s) the furniture, fixtures and equipment used at the Cancer Center Sites on the Unwind Date, including any linear accelerator then located at any Cancer Center Site. All transactions will be subject to applicable laws and regulations, including certificate of need laws. The parties agree to support any efforts to obtain governmental approval of such transactions. The purchase price for such assets will be determined pursuant to an appraisal performed by a qualified, mutually agreed independent appraiser in advance of the Unwind Date;

August 29, 2018

2:16 P.M.

each Site at which any Practice physician practiced medicine on twelve (12) or more days during the twelve (12) months prior to termination.

2.2 Term. The term of this Agreement shall commence on January 1, 2012 and continue through December 31, 2018 and shall be automatically extended and renewed so that it remains co-terminus with any extension or renewal of the Professional Services Agreement (the "*Term*").

2.3 Fair Market Value Exchange. The amounts to be paid hereunder represent the fair market value of the items and services obtained under this Agreement as established by arms-length negotiations by the parties and through an independent valuation. Such amounts have not been determined in any manner that takes into account the volume or value of any actual or potential referrals between the parties. No amount paid hereunder is intended to be, nor shall it be construed to be, an inducement or payment for referral of patients by any party to any other party, or for the purchase, order or lease, or arranging for or recommending the purchase, order or lease, of any item or service covered by a governmental or private health care payment plan. In addition, the amounts charged hereunder do not include any discount, rebate, kickback or other reduction in charges, and the amount charged is not intended to be, nor shall it be construed to be, an inducement or payment for referral of patients by any party to any other party, or for the purchase, order or lease, or arranging for or recommending the purchase, order or lease, of any item or service covered by a governmental or private health care payment plan.

2.4 Invalidity or Unenforceability of Particular Provisions. It is the intent of the parties that the terms of this Agreement be in compliance with applicable laws, statutes, rules and regulations, including, without limitation, Medicare and Medicaid provisions and provisions of the Tennessee Code. If either party determines, in good faith, based on legal opinion of nationally recognized health law counsel, or receives general or specific notice from a governmental agency that this Agreement or any part hereof: (i) violates or fails to comply with any state or federal law, regulation, rule, or administrative policy or would result in Stark law restrictions on referrals to the Methodist Hospitals, Practice or any of their affiliates; (ii) jeopardizes such party's (or any of its affiliates') participation in any federal or state health care program; (iii) jeopardizes the tax-exempt status of MLH, the Methodist Hospitals or any of their affiliates or the tax-exempt status of any bonds issued on its/their behalf; (iv) exposes any organization manager or disqualified person of MLH, the Methodist Hospitals or any their affiliates to intermediate sanctions by the Internal Revenue Service or results in private inurement or private benefit; or (v) exposes any person or party or its affiliates to any other sanctions by any other regulatory agency, such party shall notify the other party in writing of its determination and provide the other party with a copy of the legal opinion obtained, if any. The parties shall then, (x) negotiate those modifications reasonably determined to be necessary to comply with a change of law other event described in this Section 2.2; or (y) if the parties are unable to negotiate a modification within thirty (30) days of delivery of the notice, then this Agreement shall automatically terminate.

2.5 Notices. Except as provided otherwise in this Agreement, any and all notices necessary or desirable to be served hereunder shall be in writing and shall be delivered personally, sent by certified mail or overnight delivery service to the intended recipient at the address for such intended recipient set forth below, or sent by facsimile to the fax number for

**Additional
Information**

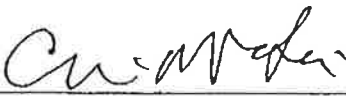
August 29, 2018

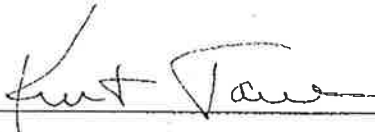
2:16 P.M.

IN WITNESS WHEREOF, the parties hereto have executed and delivered this Agreement as of the Effective Date.

METHODIST LE BONHEUR
HEALTHCARE

WEST CLINIC, PC

By: 

By: 

Its: CFD

Its: _____

**Additional
Information**

August 29, 2018

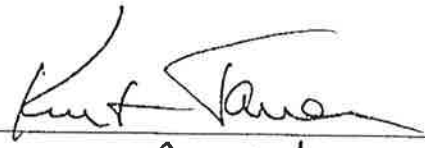
2:16 P.M.

IN WITNESS WHEREOF, the parties hereto have executed and delivered this Agreement as of the Effective Date.

**METHODIST LE BONHEUR
HEALTHCARE**

WEST CLINIC, PC

By: _____

By: 

Its: _____

Its: Vice President

Attachment B, Need, Item 1-8.d
(Project Specific Criteria-PET Service)

Cancer Incident and Mortality Chart

August 29, 2018

CANCER INCIDENCE AND MORTALITY RATES BY SITE

2010-2014

	Shelby County		Southwest Region		Tennessee	
	Incidence	Mortality	Incidence	Mortality	Incidence	Mortality
All Sites	460.6	197.5	457.8	195.5	464.0	187.2
Lung	64.6	51.4	70.3	54.9	76.1	58.3
Melanoma of the Skin	11.1	1.8	11.8	2.0	20.3	3.1
Female Breast	129.7	26.5	125.0	26.9	121.3	20.2
Prostrate	153.5	31.4	139.9	27.2	119.5	20.6
Pancreas	13.8	12.8	13.1	12.0	12.0	11.1

Note: Southwest Region includes Chester, Decatur, Fayette, Hardeman, Haywood, Henderson, Lauderdale, McNairy, Madison, Shelby and Tipton Counties.

Source: Tennessee Department of Health, Tennessee Cancer Registry Data, Cancer in Tennessee 2010-2014.

AUG 29, 2018 PM 2:16

**Additional
Information**

**August 29, 2018
2:16 P.M.**

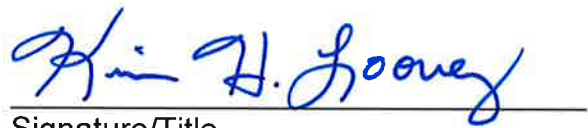
AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

NAME OF FACILITY: WEST CANCER CENTER, CN1808-038

I, KIM H. LOONEY, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.


Signature/Title

Sworn to and subscribed before me, a Notary Public, this the 29TH day of August, 2018, witness my hand at office in the County of Davidson, State of Tennessee.


NOTARY PUBLIC

My commission expires: January 8, 2019

HF-0043

Revised 7/02

